FOR USE IN MALTA

RoActemra® Dosing Guide

RoActemra® (tocilizumab) intravenous (IV) and subcutaneous (SC) formulations

A guide to assist healthcare professionals with the dose preparation and administration of RoActemra therapy in patients with:

- Rheumatoid Arthritis (RA) [Intravenous or subcutaneous]
- Giant Cell Arteritis (GCA) [Subcutaneous]
- Polyarticular Juvenile Idiopathic Arthritis (pJIA) (also referred to as Juvenile Idiopathic Polyarthritis) [Intravenous or subcutaneous]
- Systemic Juvenile Idiopathic Arthritis (sJIA) [Intravenous or subcutaneous]
- RoActemra is indicated for the treatment of chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older [Intravenous]

This RoActemra Dosing Guide is additional risk minimisation material and is provided by Roche Products (Ireland) Limited as a condition of the RoActemra marketing authorisation. It contains important safety information that you need to be aware of when administering RoActemra.

This RoActemra Dosing Guide must be read together with the RoActemra Healthcare Professional and Patient Brochures (available online at www.ema.europa.eu), the RoActemra Summary of Product Characteristics and the Package Leaflet that comes with RoActemra (and is also available on www.medicines.ie) as it contains important information about RoActemra. Please read this information carefully before administering the product.

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.ema.europa.eu and www.medicines.ie before prescribing this medicine.

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Contents

Indications and Usage

RoActemra IV (RoActemra 20 mg/ml concentrate for solution for infusion)

RoActemra, in combination with methotrexate (MTX), is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

RoActemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

RoActemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and paediatric patients 2 years of age and older.

RoActemra SC (RoActemra 162 mg solution for injection in pre-filled syringe)

RoActemra in combination with methotrexate (MTX) is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

RoActemra is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

RoActemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

RoActemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra SC (RoActemra 162 mg solution for injection in pre-filled pen)

RoActemra, in combination with methotrexate (MTX), is indicated for:

- the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

RoActemra is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

Prior to starting treatment with RoActemra:

- It is important that you review the baseline checklist found under section “General Recommendations” in the Healthcare Professional (HCP) Brochure with your patient, the patient’s parents/guardians, or both.
- Allow ample time to discuss any questions your patient, the patient’s parents/guardians, or both may have.
- It is important that you review the information contained within the RoActemra Healthcare Professional (HCP) Brochure for RoActemra® (tocilizumab) intravenous (IV) and subcutaneous (SC) formulations and the RoActemra Patient Brochure with your patient, the patient’s parents/guardians, or both. These will help them understand what they may expect from the treatment of the patient’s condition with RoActemra.

For full information, see the Summary of Product Characteristics (SmPC) and the RoActemra Package Leaflet: Information for the user, which can be found on the European Medicines Agency website (www.ema.europa.eu) or www.medicines.ie.

RoActemra Patient Brochures and other information can be requested from Roche – please see relevant contact details at the end of this brochure. If you have questions or concerns, please call Roche Medical Information on 00 353 (0)1 4690700.

Part I – Intravenous (IV) administration of RoActemra by infusion

This section will walk you through the RoActemra infusion process in 6 steps

Before therapy begins

Before beginning RoActemra therapy, it is important that you review the Package Leaflet and the Patient Brochure with each patient. This dosing guide contains valuable information that will help your patients fully understand what they may expect from their treatment.

- RoActemra alert cards and other information can be requested from your sales representative or Medical Information. If you have questions or concerns, please email Ireland.druginfo@roche.com or call 00 353 (0)1 4690700.
- Detailed information on this medicine is available on the European Medicines Agency website (www.ema.europa.eu).

1. Weigh patient and calculate RoActemra dose based on indication

RoActemra dosing is calculated based on each patient's weight and the indication for which they are treated. The treatment frequency varies by indication. Verify the patient's weight and indication, then locate it on the chart (included on the following pages) to find the corresponding dose and recommended vial combination.

If the patient's dose has been calculated prior to the infusion date, take his or her weight again to make sure that it has not changed from the time of the original calculation to require a change in dose. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the relevant chart to check whether a dosing adjustment is necessary.

Once the dose is calculated, choose the vial combination of RoActemra that best matches the patient's needs. RoActemra is available in three different dosing vials:

400 mg (20 ml) vials

200 mg (10 ml) vials

80 mg (4 ml) vials

Inspect the vials for particulate matter and discolouration.

RA: Dosing Preparation and Administration Guide with RoActemra IV

RoActemra IV dosing in RA patients is calculated based on each patient's weight as follows:

For the 8 mg/kg dose: Patient weight (kg) x 8 (mg/kg) = RoActemra dose.

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended.

Doses above 1.2 g have not been evaluated in clinical studies.

Dosing should take place at 4-week intervals.

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
8 mg/kg	50	110.0	400	20.0	1 × 400 mg
	52	114.4	416	20.8	1 × 400 mg + 1 × 80 mg
	54	118.8	432	21.6	1 × 400 mg + 1 × 80 mg
	56	123.2	448	22.4	1 × 400 mg + 1 × 80 mg
	58	127.6	464	23.2	1 × 400 mg + 1 × 80 mg
	60	132.0	480	24.0	1 × 400 mg + 1 × 80 mg
	62	136.4	496	24.8	1 × 400 mg + 1 × 80 mg + 1 × 80 mg + 1 × 80 mg
	64	140.8	512	25.6	1 × 400 mg + 1 × 80 mg + 1 × 80 mg + 1 × 80 mg
	66	145.2	528	26.4	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	68	149.6	544	27.2	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	70	154.0	560	28.0	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	72	158.4	576	28.8	1 × 400 mg + 1 × 400 mg
	74	162.8	592	29.6	1 × 400 mg + 1 × 400 mg
	76	167.2	608	30.4	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	78	171.6	624	31.2	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	80	176.0	640	32.0	1 × 400 mg + 1 × 80 mg + 1 × 80 mg
	82	180.4	656	32.8	1 × 400 mg + 1 × 400 mg + 1 × 80 mg
	84	184.8	672	33.6	1 × 400 mg + 1 × 400 mg + 1 × 80 mg
	86	189.2	688	34.4	1 × 400 mg + 1 × 80 mg + 1 × 80 mg + 1 × 80 mg
	88	193.6	704	35.2	1 × 400 mg + 1 × 80 mg + 1 × 80 mg + 1 × 80 mg
	90	198.0	720	36.0	1 × 400 mg + 1 × 80 mg + 1 × 80 mg + 1 × 80 mg
	92	202.4	736	36.8	1 × 400 mg + 1 × 400 mg + 1 × 80 mg
	94	206.8	752	37.6	1 × 400 mg + 1 × 400 mg + 1 × 80 mg
	96	211.2	768	38.4	1 × 400 mg + 1 × 400 mg
	98	215.6	784	39.2	1 × 400 mg + 1 × 400 mg
	≥100	≥220.0	800	40.0	1 × 400 mg + 1 × 400 mg

pJIA: Dosing Preparation and Administration Guide with RoActemra IV

RoActemra IV dosing in pJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 10 mg/kg = RoActemra dose.

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = RoActemra dose.

Dosing should take place at 4-week intervals.

The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a consistent change in the patient's body weight over time. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
10 mg/kg	10	22.0	100	5.0	1 + 1
	12	26.4	120	6.0	1 + 1
	14	30.8	140	7.0	1 + 1
	16	35.2	160	8.0	1 + 1
	18	39.6	180	9.0	1
	20	44.0	200	10.0	1
	22	48.4	220	11.0	1 + 1 + 1
	24	52.8	240	12.0	1 + 1 + 1
	26	57.2	260	13.0	1 + 1
	28	61.6	280	14.0	1 + 1
8 mg/kg	30	66.0	240	12.0	1 + 1 + 1
	32	70.4	256	12.8	1 + 1
	34	74.8	272	13.6	1 + 1
	36	79.2	288	14.4	1 + 1 + 1 + 1
	38	83.6	304	15.2	1 + 1 + 1 + 1
	40	88.0	320	16.0	1 + 1 + 1 + 1
	42	92.4	336	16.8	1 + 1 + 1
	44	96.8	352	17.6	1 + 1 + 1
	46	101.2	368	18.4	1
	48	105.6	384	19.2	1
	50	110.0	400	20.0	1
	52	114.4	416	20.8	1 + 1 + 1 + 1
	54	118.8	432	21.6	1 + 1 + 1 + 1
	56	123.2	448	22.4	1 + 1
	58	127.6	464	23.2	1 + 1
	60	132.0	480	24.0	1 + 1
	62	136.4	496	24.8	1 + 1 + 1 + 1 + 1
	64	140.8	512	25.6	1 + 1 + 1 + 1 + 1
	66	145.2	528	26.4	1 + 1 + 1
	68	149.6	544	27.2	1 + 1 + 1
	70	154.0	560	28.0	1 + 1 + 1
	72	158.4	576	28.8	1 + 1
	74	162.8	592	29.6	1 + 1
	76	167.2	608	30.4	1 + 1 + 1 + 1
	78	171.6	624	31.2	1 + 1 + 1 + 1
	80	176.0	640	32.0	1 + 1 + 1 + 1
	82	180.4	656	32.8	1 + 1 + 1
	84	184.8	672	33.6	1 + 1 + 1
	86	189.2	688	34.4	1 + 1 + 1 + 1 + 1
	88	193.6	704	35.2	1 + 1 + 1 + 1 + 1
	90	198.0	720	36.0	1 + 1 + 1 + 1 + 1
	92	202.4	736	36.8	1 + 1 + 1 + 1
	94	206.8	752	37.6	1 + 1 + 1 + 1
	96	211.2	768	38.4	1 + 1
	98	215.6	784	39.2	1 + 1
	≥100	≥220.0	800	40.0	1 + 1

sJIA: Dosing Preparation and Administration Guide with RoActemra IV

RoActemra IV dosing in sJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 12 mg/kg = RoActemra dose.

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = RoActemra dose.

Dosing should take place at 2-week intervals.

The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a consistent change in the patient's body weight over time. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
12 mg/kg	10	22.0	120	6.0	🟢 + 🟢
	12	26.4	144	7.2	🟢 + 🟢
	14	30.8	168	8.4	🟡
	16	35.2	192	9.6	🟡
	18	39.6	216	10.8	🟢 + 🟢 + 🟢
	20	44.0	240	12.0	🟢 + 🟢 + 🟢
	22	48.4	264	13.2	🟡 + 🟢
	24	52.8	288	14.4	🟢 + 🟢 + 🟢 + 🟢
	26	57.2	312	15.6	🟢 + 🟢 + 🟢 + 🟢
	28	61.6	336	16.8	🟡 + 🟢 + 🟢
8 mg/kg	30	66.0	240	12.0	🟢 + 🟢 + 🟢
	32	70.4	256	12.8	🟡 + 🟢
	34	74.8	272	13.6	🟡 + 🟢
	36	79.2	288	14.4	🟢 + 🟢 + 🟢 + 🟢
	38	83.6	304	15.2	🟢 + 🟢 + 🟢 + 🟢
	40	88.0	320	16.0	🟢 + 🟢 + 🟢 + 🟢
	42	92.4	336	16.8	🟡 + 🟢 + 🟢
	44	96.8	352	17.6	🟡 + 🟢 + 🟢
	46	101.2	368	18.4	🟡
	48	105.6	384	19.2	🟡
	50	110.0	400	20.0	🟡
	52	114.4	416	20.8	🟡 + 🟢 + 🟢 + 🟢
	54	118.8	432	21.6	🟡 + 🟢 + 🟢 + 🟢
	56	123.2	448	22.4	🟡 + 🟢
	58	127.6	464	23.2	🟡 + 🟢
	60	132.0	480	24.0	🟡 + 🟢
	62	136.4	496	24.8	🟡 + 🟢 + 🟢 + 🟢 + 🟢
	64	140.8	512	25.6	🟡 + 🟢 + 🟢 + 🟢 + 🟢
	66	145.2	528	26.4	🟡 + 🟢 + 🟢
	68	149.6	544	27.2	🟡 + 🟢 + 🟢
	70	154.0	560	28.0	🟡 + 🟢 + 🟢
	72	158.4	576	28.8	🟡 + 🟡
	74	162.8	592	29.6	🟡 + 🟡
	76	167.2	608	30.4	🟡 + 🟢 + 🟢 + 🟢
	78	171.6	624	31.2	🟡 + 🟢 + 🟢 + 🟢
	80	176.0	640	32.0	🟡 + 🟢 + 🟢 + 🟢
	82	180.4	656	32.8	🟡 + 🟡 + 🟢
	84	184.8	672	33.6	🟡 + 🟡 + 🟢
	86	189.2	688	34.4	🟡 + 🟢 + 🟢 + 🟢 + 🟢
	88	193.6	704	35.2	🟡 + 🟢 + 🟢 + 🟢 + 🟢
	90	198.0	720	36.0	🟡 + 🟢 + 🟢 + 🟢 + 🟢
	92	202.4	736	36.8	🟡 + 🟡 + 🟢 + 🟢
	94	206.8	752	37.6	🟡 + 🟡 + 🟢 + 🟢
	96	211.2	768	38.4	🟡 + 🟡
	98	215.6	784	39.2	🟡 + 🟡
	≥100	≥220.0	800	40.0	🟡 + 🟡

CRS: Dosing Preparation and Administration Guide with RoActemra IV

RoActemra dosing in CRS patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 12 mg/kg = RoActemra dose.

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = RoActemra dose.

If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of RoActemra may be administered. The interval between consecutive doses should be at least 8 hours.

Doses exceeding 800 mg per infusion are not recommended in CRS patients.

Subcutaneous administration is not approved for CRS.

2. Gather all necessary supplies

You will need:

- RoActemra at room temperature
- Syringes and large-bore needles
- One primary infusion set
- One 50 ml (patients <30 kg) or 100 ml (patients ≥30 kg) bag of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection
- One intravenous (IV) catheter
- Gauze
- Tourniquet
- Gloves
- Alcohol/cleansing wipes

3. Take baseline assessments

Take baseline assessments to ensure the patient is healthy enough to receive the infusion.

Vital signs may include:

- Blood pressure
- Temperature
- Pulse

Follow the recommended baseline patient questions as described in the RoActemra Healthcare Professional Brochure (General Recommendation) as well as the Summary of Product Characteristics (Section 4.4 – Warnings and Precautions).

4. Prepare the patient for the infusion

RoActemra does not require premedication.

Review the Package Leaflet and the Patient Brochure with the patient and answer any questions he or she might have.

5. Prepare the RoActemra infusion

RoActemra should not be infused concomitantly in the same IV line with other medications.

No physical or biochemical compatibility studies have been conducted to evaluate the co administration of RoActemra with other medications.

RoActemra is a ready-mix solution and requires no reconstitution. The expiry date should always be checked before use. The RoActemra concentrate for IV infusion should be diluted to a final volume of 100 ml (patients ≥30 kg) and to a final volume of 50 ml (patients <30 kg), by a healthcare professional using aseptic technique.

- RoActemra should be refrigerated for storage and the fully diluted RoActemra solution should be allowed to reach room temperature before it is infused.
- The fully diluted RoActemra solutions for infusion may be stored at 2°C–8°C or room temperature (if diluted under controlled and validated aseptic conditions) for up to 24 hours and should be protected from light.
- RoActemra solutions do not contain preservatives; therefore, unused product remaining in the vials should not be used.
- **Weight-/indication-based dosing:**
  - **For RA, CRS (≥30 kg), sJIA (≥30 kg), and pJIA (≥30 kg):**
    From a 100 ml infusion bag withdraw a volume of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the RoActemra solution required for the patient's dose.

    Withdraw the required amount of RoActemra concentrate (**0.4 mL/kg**) from the vial and place in the 100 mL infusion bag. This should be a final volume of 100 mL. To mix the solution, gently invert the infusion bag to avoid foaming.
  - **For sJIA, and CRS patients <30 kg:**
    From a 50 ml infusion bag withdraw a volume of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the RoActemra solution required for the patient's dose.

    Withdraw the required amount of RoActemra concentrate (**0.6 mL/kg**) from the vial and place in the 50 mL infusion bag. This should be a final volume of 50 mL. To mix the solution, gently invert the infusion bag to avoid foaming.
  - **For pJIA patients <30 kg:**
    From a 50 ml infusion bag withdraw a volume of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the RoActemra solution required for the patient's dose.

    Withdraw the required amount of RoActemra concentrate (**0.5 mL/kg**) from the vial and place in the 50 mL infusion bag. This should be a final volume of 50 mL. To mix the solution, gently invert the infusion bag to avoid foaming.

- RoActemra should not be infused concomitantly in the same IV line with other medications. No physical or biochemical compatibility studies have been conducted to evaluate the co-administration of RoActemra with other medications.
- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. Only solutions which are clear to opalescent, colourless to pale yellow and free of visible particles should be diluted.
- Dispose of needle and syringe in accordance with local requirements when finished.

6. Begin the RoActemra infusion

The infusion should be administered over one hour. It must be administered with an infusion set and should never be administered as an IV push or bolus.

Prior to the infusion, inform the patient that serious allergic reactions including anaphylaxis have been reported in association with RoActemra. Such reactions may be more severe, and potentially fatal, in patients who have experienced allergic reactions during previous treatment with RoActemra even if they have received premedication with steroids and antihistamines. Most allergic reactions occur during infusion or within 24 hours of RoActemra administration, although allergic reactions can occur at any time.

If an anaphylactic reaction or other serious hypersensitivity/serious infusion-related reaction occurs, administration of RoActemra should be stopped immediately, appropriate therapy initiated and RoActemra should be permanently discontinued. Fatal anaphylaxis has been reported after marketing authorisation during treatment with RoActemra IV.

Instruct the patient to **seek immediate medical attention** if they notice any of the following signs or symptoms of systemic allergic reactions:

- Rash, itching or hives
- Shortness of breath or trouble breathing
- Swelling of the lips, tongue or face
- Chest pain
- Feeling dizzy or faint
- Severe stomach pain or vomiting
- Hypotension

Once the infusion is completed, remove the catheter and dispose of all supplies properly, clean and bandage the infusion site and check the patient's vital signs.

Part II – SC administration of RoActemra by injection using either the pre-filled syringe (PFS) or pre-filled pen (ACTPen)

The PFS is used in RA (162 mg once per week), GCA (162 mg once every week in combination with a tapering course of glucocorticoids), pJIA (162 mg once every 2 weeks in patients weighing ≥30 kg or once every 3 weeks in patients weighing <30 kg), and sJIA (162 mg once every week in patients weighing ≥30 kg or 162 mg once every 2 weeks in patients <30 kg) indications only.

The ACTPen is used in RA (162 mg once per week) and GCA (162 mg once every week in combination with a tapering course of glucocorticoids) indications only.

Instructions apply to both devices. Device-specific instructions are included in colour coded sections (pre-filled syringe = green; pre-filled pen (ACTPen) = orange).

This section will walk you through the RoActemra injection process using a pre-filled syringe in 5 steps

1. Gather all necessary supplies

You will need:

- One RoActemra PFS OR ACTPen at room temperature
- A well-lit, clean, flat surface
- Sharps container
- Alcohol pad/cleansing wipes
- Sterile cotton ball or gauze
- Clock or watch

2. Take baseline assessments

The first injection using the RoActemra SC devices should be performed under the supervision of a qualified healthcare professional.

Prior to initiation, it is important to take baseline assessments to ensure the patient is healthy enough to receive the injection.

Vital signs may include:

- Blood pressure
- Temperature
- Pulse

Follow the recommended baseline patient questions as described in the RoActemra Healthcare Professional Brochure (General Recommendations) as well as the Summary of Product Characteristics (Section 4.4 – Warnings and Precautions).

3. Preparation for injection

- Store the RoActemra SC device at 2°C–8°C. Do not freeze.
- Allow the device to reach room temperature (**18°C to 28°C**) after removing it from the refrigerator. Do not warm up the device in any other way.
  - **Do not** speed up the warming process in any way, such as using the microwave or placing in warm water.
  - **Do not** leave the device to warm up in direct sunlight.
- Do not shake the device.
- Do not reuse the device.
- Do not try to take apart the device at any time.
- Do not use the device through clothing.

Before every use:

- **Check the RoActemra SC device to make sure it is not damaged**.
- Do not use if it appears to be damaged or if you have accidentally dropped it.
- If you are opening the box for the first time, check to make sure that it is properly sealed. Do not use the device if the box looks like it has already been opened.
- Check that the device box is not damaged. Do not use device if the box looks damaged.
- Check the expiration date on device. Do not use the RoActemra SC device if the expiration date has passed because it may not be safe to use. If the expiration date has passed, safely dispose of the device in a sharps container and get a new one.
- Inspect the RoActemra SC device visually for particulate matter and discolouration prior to administration and check the expiration date. Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to slightly yellowish, or if any part of it appears to be damaged.
- Do not leave the RoActemra SC device unattended. Keep out of the reach of children.
- Stop administration of RoActemra immediately if an anaphylactic reaction or other serious hypersensitivity reaction occurs. Initiate appropriate therapy and permanently discontinue RoActemra.

Injection Preparation: RoActemra PFS

RoActemra 162 mg is supplied in 0.9 ml of solution for injection as a pack of 4 single-use pre-filled syringes.

- They should be kept in the outer carton to protect them from light and should be kept dry. The pre-filled syringes should be kept out of sight and reach of children.
- Administer RoActemra 162 mg/0.9 ml within 8 hours once you remove it from the refrigerator and do not keep it above 30°C.
- Allow the PFS to reach room temperature and wait for about 25 to 30 minutes before injecting RoActemra 162 mg/0.9 ml.
- Start the injection within 5 minutes after removing the cap, to prevent the medicine from drying out and blocking the needle.

Injection Preparation: RoActemra ACTPen

- Do not remove the ACTPen cap until you are ready to inject RoActemra.
- Take the box containing the ACTPen out of the refrigerator.
- Open the box and remove one single-use RoActemra ACTPen from the box.
- Return any remaining ACTPens in the box to the refrigerator.
- Place the ACTPen on a clean, flat surface and let it warm up for 45 minutes to allow it to reach room temperature. If the ACTPen does not reach room temperature, this could cause your injection to feel uncomfortable and it could take longer to inject.

4. Choose and prepare an injection site

- Wash your hands with soap and water.
- Clean the chosen injection site area using the alcohol pad to reduce the risk of infection. Let the skin dry for approximately 10 seconds. Be sure not to touch the cleaned area prior to the injection. Do not fan or blow on the clean area.
- The front of your thigh or your abdomen except for the 2-inch (5cm) area around your navel are the recommended injection sites **(see Figure A)**.
- The outer area of the upper arms may also be used only if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself **(see Figure A)**.
- **Rotate Injection Site**
  Choose a different injection site for each new injection, at least:
  - **PFS: 1.5 inch (3 cm) from the area you used for your previous injection**.
  - **ACTPen: 1 inch (2.5cm) from the last area you injected**.
- Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact. Do not inject into areas that could be bothered by a belt or waistband.

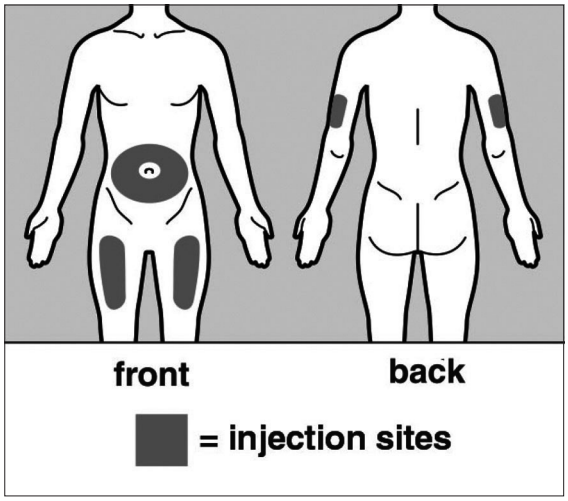


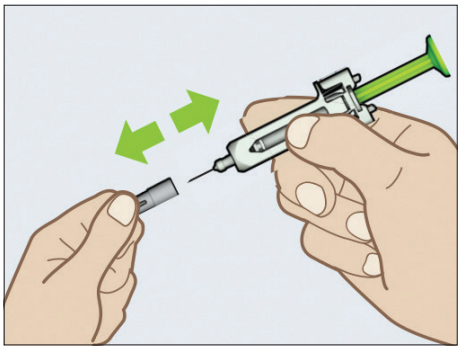
Figure A

5a. Administering the injection with the pre-filled syringe for RA, GCA, pJIA and sJIA

Step 1 – Remove needle cap

When ready to inject, firmly grip the syringe with one hand and pull the cap straight off with the other hand. Discard the cap. Do not pull or press the plunger, and do not shake the pre-filled syringe. After removing the needle cap, the injection must be started within **5 minutes** to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of removing the cap, you must dispose of it in a sharps container and use a new pre-filled syringe. A small drop of liquid at the needle tip is normal.

Never re-attach the needle cap after removal.



Step 2 – Pinch skin and insert needle, release skin

Pinch the skin at the injection site to provide a firm surface for injection.

Insert the needle with a quick, firm action. The needle must be inserted all the way in at an angle between 45° and 90°.

Keep the syringe in position and release the pinched skin.

It is important to choose the correct angle (between 45° and 90°) to ensure the medication is delivered under the skin, otherwise the injection could be painful and the medication may not be administered correctly.

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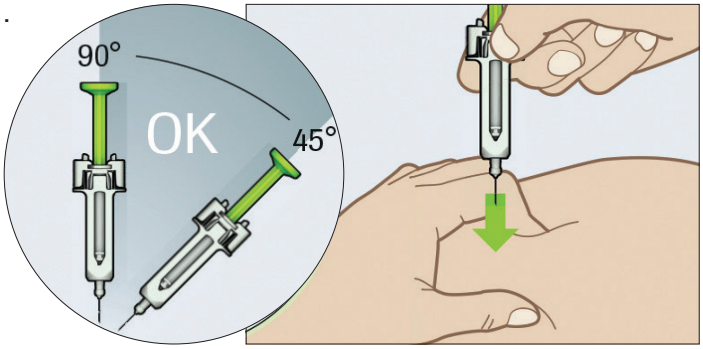


Step 3 – Slowly press down all the way then remove

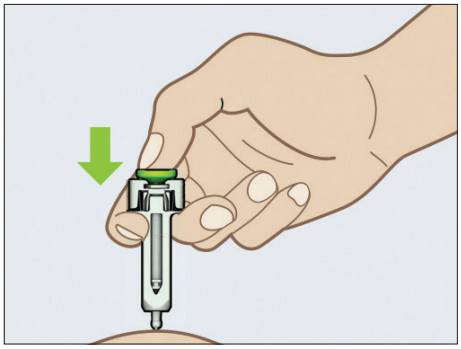
Slowly inject all the medicine by gently pushing the plunger all the way down.

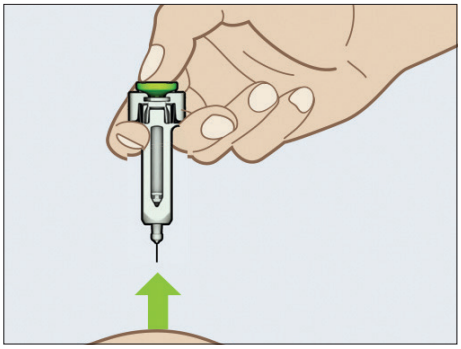
Keep an even pressure on the plunger and don't release the pressure once the injection has started.

Once the plunger is pushed all the way down, keep pressing down on the plunger to be sure all of the medicine is injected before taking the needle out of the skin.

Keep pressing down on the plunger while you take the needle out of the skin at the same angle as inserted.

If, following insertion of the needle, you cannot depress the plunger, you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe.



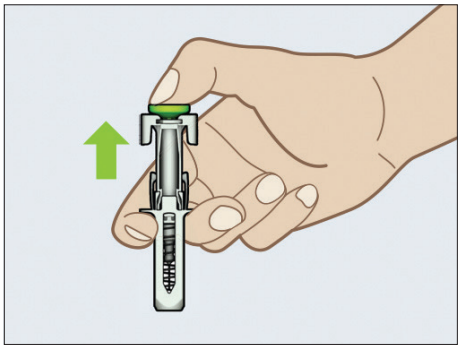


Step 4 – Release plunger and dispose

Once the needle is completely removed from the skin, release the plunger. This will automatically activate the needle shield.

Press gently on the injection area with a cotton wool ball or gauze swab.

Throw away the used syringe in a sharps container.



If the plunger is not fully depressed the needle shield will not extend to cover the needle when it is removed, and the patient may not have received the full dose of RoActemra:

- **Do not** touch the needle shield of the pre-filled syringe to avoid a needle-stick injury
- **Do not** try to re-use the pre-filled syringe
- **Do not** repeat the injection with another pre-filled syringe

5b. Administering the injection with the pre-filled pen for RA and GCA

What you need to know to use your RoActemra pre-filled pen (ACTPen) safely
Read and follow the Instructions for Use that come with your RoActemra pre-filled pen before you start using it and each time you get a prescription refill. Before you use the RoActemra pre-filled pen for the first time, make sure your healthcare provider shows you the right way to use it.

Important: Keep your unused pre-filled pens in the original carton and keep in the refrigerator at 2˚C to 8˚C (36˚F to 46˚F). **Do not freeze**.

- **Do not remove the pre-filled pen cap until you are ready to inject RoActemra.**
- **Do not try to take apart the pre-filled pen at any time.**
- **Do not reuse the same pre-filled pen.**
- **Do not use the pre-filled pen through clothing.**
- **Do not leave the pre-filled pen unattended.**
- **Keep out of the reach of children.**

Parts of your RoActemra pre-filled pen **(See Figure B)**.

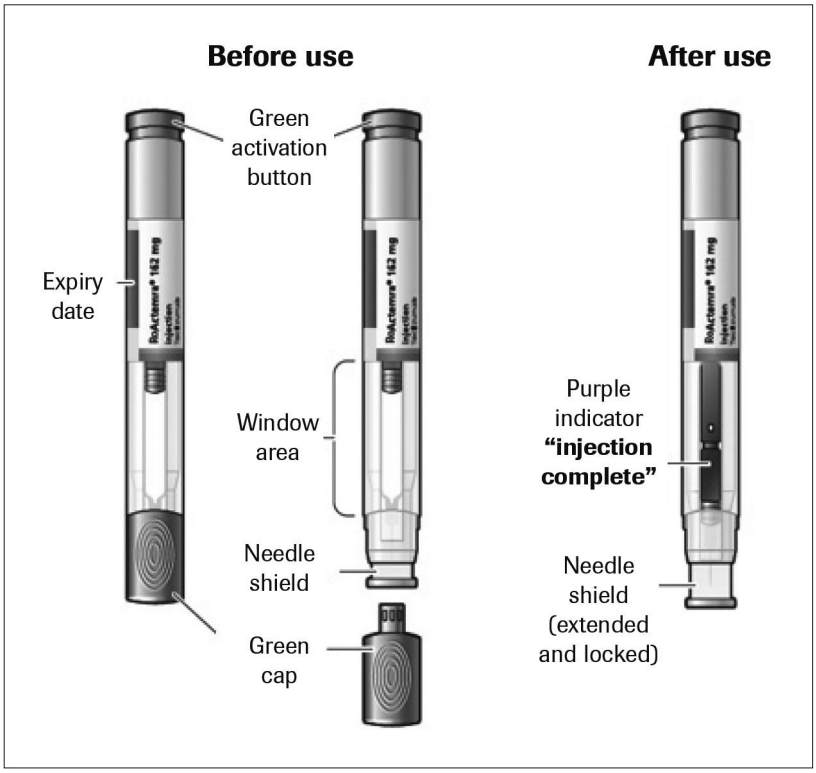


Figure B

Step 1 – Preparing for a RoActemra ACTPen Injection

Do not remove the green cap while allowing your RoActemra pre-filled pen to reach room temperature.

- Hold your RoActemra pre-filled pen with the green cap pointing down **(See Figure C)**.
- Look in the clear Window area. Check the liquid in the RoActemra pre-filled pen **(See Figure C)**. It should be clear and colourless to pale yellow. **Do not** inject RoActemra if the liquid is cloudy, discoloured, or has lumps or particles in it because it may not be safe to use. Safely dispose of the pre-filled pen in a sharps container and get a new one.
- Wash your hands well with soap and water.

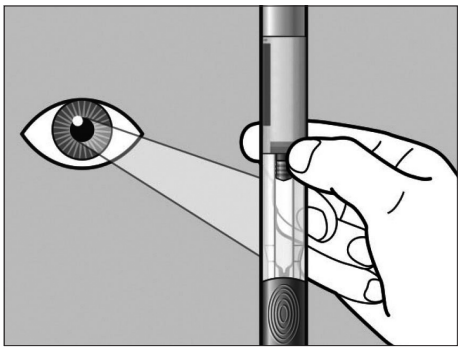


Figure C

Step 2 – Inject RoActemra

Hold the RoActemra pre-filled pen firmly with one hand. Twist and pull off the green cap with the other hand **(See Figure D)**. The green cap contains a loose fitting metal tube.

If you cannot remove the green cap you should ask a caregiver for help or contact your healthcare provider.

Important: Do not touch the needle shield which is located at the tip of the pre-filled pen below the Window area (see Figure A), to avoid accidental needle stick injury.

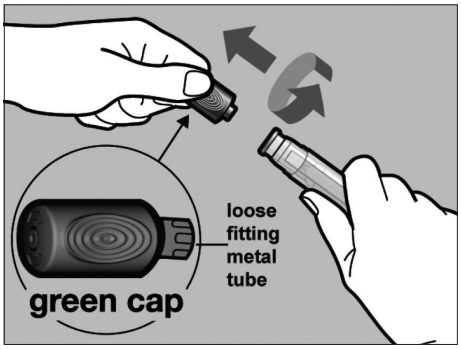


Figure D

Throw away the green cap in a sharps container.

After you remove the green cap, the pre-filled pen is ready for use. If the pre-filled pen is not used within 3 minutes of the cap removal, the pre-filled pen should be disposed of in the sharps container and a new pre-filled pen should be used.

Never reattach the green cap after removal.

Hold the pre-filled pen comfortably in 1 hand by the upper part, so that you can see the Window area of the pre-filled pen **(See Figure E)**.

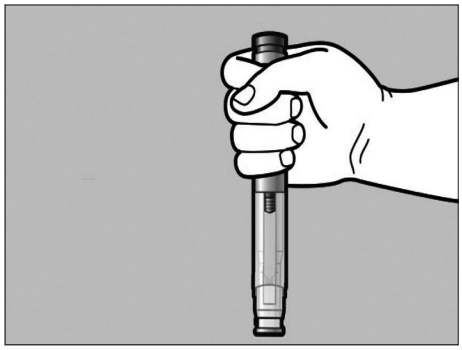


Figure E

Use your other hand to gently pinch the area of skin you cleaned, to prepare a firm injection site **(See Figure F)**. The pre-filled pen requires a firm injection site to properly activate. Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could cause the injection to feel uncomfortable.

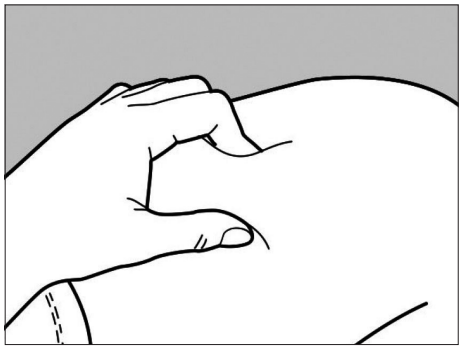


Figure F

Do not press the green activation button yet.

Place the needle-shield of the pre-filled pen against your pinched skin at a 90° angle **(See Figure G)**.

It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful and the medicine may not work.

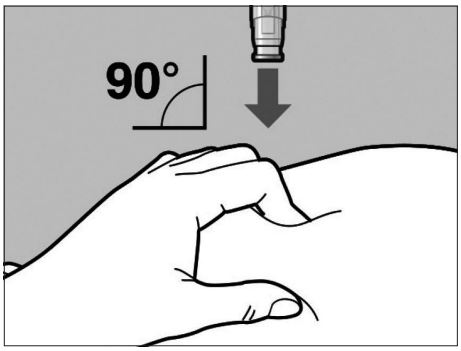


Figure G

To use the pre-filled pen, you first have to unlock the green Activation button.

To unlock it, press the pre-filled pen firmly against your pinched skin until the needle-shield is completely pushed in **(See Figure H)**.

Continue to keep the needle-shield pushed in.

If you don't keep the needle-shield completely pushed against the skin, the green Activation button will not work.

Continue to pinch the skin while you keep the pre-filled pen in place.

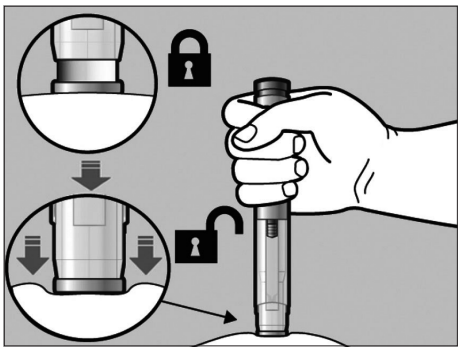


Figure H

Press the green Activation button to start the injection. A “click” sound indicates the start of the injection. Keep the green button pressed in and continue holding the pre-filled pen pressed firmly against your skin **(See Figure I)**. If you cannot start the injection you should ask for help from a caregiver or contact your healthcare provider.

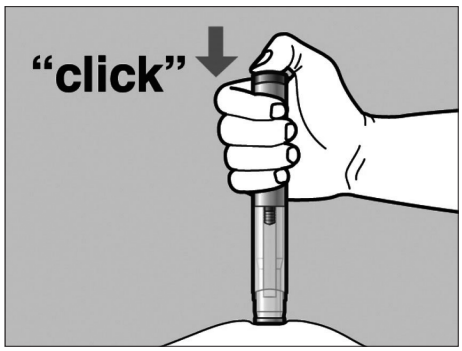


Figure I

The purple indicator will move along the Window area during the injection **(See Figure J)**.

Watch the purple indicator until it stops moving to be sure the full dose of medication is injected.

The injection may take up to **10 seconds**.

You may hear a second “click” during the injection but you should continue to hold the pre-filled pen firmly against your skin until the purple indicator stops moving.

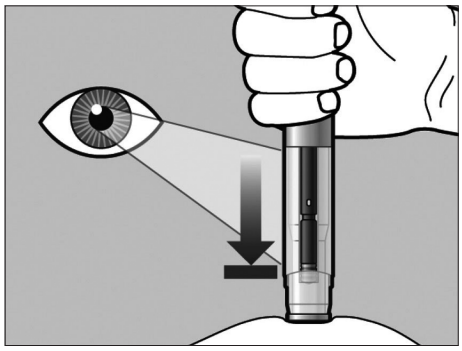


Figure J

When the purple indicator has stopped moving, release the green button. Lift the pre-filled pen straight off of the injection site at a 90° angle to remove the needle from the skin. The needle-shield will then move out and lock into place covering the needle **(See Figure K)**.

Check the Window area to see that it is filled with the purple indicator **(See Figure K)**.

If the Window area is not filled by the purple indicator then the needle-shield may not have locked. **Do not** touch the needle-shield of the pre-filled pen, because you may stick yourself with the needle. If the needle is not covered, carefully place the pre-filled pen into the sharps container to avoid any injury with the needle.

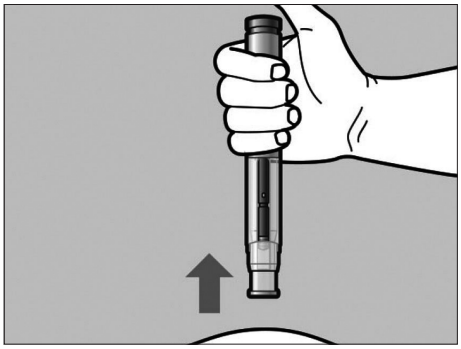


Figure K

You may not have received your full dose of RoActemra. Do not try to re-use the pre-filled pen. **Do not** repeat the injection with another pre-filled pen. Call your healthcare provider for help.

After the Injection

There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.

Do not rub the injection site.

If needed, you may cover the injection site with a small bandage.

Step 3 – Dispose of the pre-filled pen

The RoActemra pre-filled pen should not be reused. Put the used pre-filled pen into your sharps container. Do not put the cap back on the pre-filled pen.

If your injection is given by another person, this person must also be careful when removing the pre-filled pen and disposing of it to prevent accidental needle stick injury and passing infection.

Put your used RoActemra pre-filled pen and green cap in a sharps disposal container right away after use **(See Figure L)**.

Do not throw away (dispose of) the pre-filled pen and the green cap in your household trash and do not recycle it.

Always keep the puncture-resistant container out of the sight and reach of children.

Keep the RoActemra pre-filled pen and disposal container out of the reach of children.

Record your injection.

Product traceability

In order to improve the traceability of biological medicinal products, the trade name and batch number of the administered product should be clearly recorded (or stated) in the patient file.

If you have any questions or concerns about your RoActemra pre-filled pen, talk to your healthcare provider familiar with RoActemra.

Figure L

If your patient would like more information about RoActemra, please direct them to the Patient Information Leaflet or contact Ireland.druginfo@roche.com or to call 00 353 (0)1 4690700.

Detailed information on this medicine is available on the European Medicines Agency website (www.ema.europa.eu) and www.medicines.ie.

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions (see details below).

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:
http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

For electronic copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material.
Alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone [00 353 (0)1 4690700] or email [ireland.drug_surveillance_centre@roche.com].

For further information about this medicine, please contact Medical Information at Roche Products (Ireland) Limited by telephone [00 353 (0)1 4690700] or email [Ireland.druginfo@roche.com].

MT v25.1.0
Zinc Number: IE/RACTE/1119/0014f
Date of Preparation: November 2019
Date of Malta Medicines Authority Approval: December 2019