

Package leaflet: Information for the user

ARFEN 125 mg suppositories

ARFEN 250 mg suppositories

ARFEN 500 mg suppositories

Paracetamol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Arfen is and what it is used for
2. What you need to know before you use Arfen
3. How to use Arfen
4. Possible side effects
5. How to store Arfen
6. Contents of the pack and other information

1. What Arfen is and what it is used for

Arfen contains paracetamol, which acts to relieve pain (analgesic) and decrease fever (antipyretic).

Arfen is indicated to treat pain and a high temperature (fever). It is used for the relief of mild to moderate pain and feverish conditions, earache, toothache, colds, influenza, traumatic, muscular and joint pain and period pains.

Arfen can be used in hyperergic reactions after vaccination and as analgesic before and after surgical interventions.

Arfen 500 mg is also indicated to relief headache, migraine with prior medical diagnosis and osteoarthritis pain.

2. What you need to know before you use Arfen

Do not use Arfen if:

- You are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6)
- You have severe liver disease.
- You have disorders of blood cell formation.

Warnings and precautions

Talk to your doctor or pharmacist before using Arfen.

- If you have kidney problems.
- If you have liver problems (for example, if you suffer from a liver disease called hepatitis or inflammation due to prolonged alcohol consumption)
- If you have a rare metabolic disease, called Gilbert's disease (or Meulengracht's disease), where your skin and/or eyes turn yellow.
- If you have disease called glucose-6-dehydrogenase deficiency.
- If you have hemolytic anemia
- In case of suffering alcoholism
- If you suffer from dehydration and chronic malnutrition.

Incorrect use of large amounts of pain medication (pain relievers) for an extended period of time can cause headache. Do not treat these headaches with larger doses of paracetamol.

Prolonged or frequent administration of this medicine is not recommended. Prolonged use of this medication can cause kidney changes.

The risk of overdose is greater in those with liver disease of non-cirrhotic alcoholic origin. Precautions should be taken in case of chronic alcoholism. In this case, the daily dose should not exceed 2 grams.

Do not use Arfen without talking to your doctor if:

- You have a high fever (over 39°C)
- Fever lasts for more than 3 days
- The fever disappears and then reappears (recurrent fever).

These situations may require evaluation and treatment by the doctor.

Children and adolescents

Arfen 125 mg suppositories are intended for rectal administration in children under 2 years old.

Arfen 250 mg suppositories are intended for rectal administration in children between 2 and 12 years old.

Arfen 500 mg suppositories is not suitable for the treatment of children under the age of 12 and a body weight of less than 40 kg, due to the amount of paracetamol. For these patients, other forms of presentation are available that contain more adequate amounts of paracetamol.

Other medicines and Arfen

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

It is important to tell the doctor if you are taking:

- warfarin (blood thinners).
- probenecid (used for gout).
- phenytoin (antiepileptic drug).
- phenobarbital (antiepileptic drug).
- carbamazepine (antiepileptic drug).
- sedatives.
- rifampicin (anti-tuberculosis drugs).
- cholestyramine (medicine for high blood fats).
- chloramphenicol (drug used in bacterial infections).
- zidovudine (antiviral).
- St. John's wort extract (included in some herbal remedies).

Do not use other medicines containing paracetamol during treatment with Arfen.

Arfen with food and drink

Do not drink alcohol during treatment with paracetamol. Alcohol can increase the toxicity of paracetamol in the liver.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

If necessary, Arfen can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breast-feeding

Paracetamol is excreted in breast milk, but it is unlikely to affect breast-fed babies. Tell your doctor for advice if you use Arfen more than occasionally during lactation.

Driving and using machines

Arfen does not affect your ability to drive or use machinery.

However, you should avoid these activities if you experience mild drowsiness or dizziness, which are side effects of the medicine.

3. How to use Arfen

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose. There is a risk of very serious liver damage.

Use in children and adolescents

The recommended dose depends on age and body weight.

The recommended single dose is 10 – 20 mg/kg body weight, up to a maximum of 60 mg/kg body weight of total daily dose.

The interval between doses should be at least 6 hours.

The maximum daily dose of paracetamol should not exceed 3 g/day.

This dosing schedule is only indicative, and it is necessary to take into account the doctor's recommendations:

Age	Approx. body weight	Dose	Maximum daily dose (24 hours)
6 – 9 months	7 – 8 kg	1 suppository of 125mg	3 suppositories (equivalent to 375 mg paracetamol)
9 months up to 2 years	8 – 12 kg	1 suppository of 125mg	3-4 suppositories (equivalent to 375 mg – 500 mg paracetamol)
2 – 4 years	12 – 16 kg	1 suppository of 250mg	3 suppositories (equivalent to 750 mg paracetamol)
4 – 8 years	16 – 25 kg	1 suppository of 250mg	3-4 suppositories (equivalent to 750 mg – 1000 mg of paracetamol)
8 – 12 years	25 – 40 kg	1 – 2 suppositories of 250mg	4 suppositories (equivalent to 1000 mg of paracetamol)

Age	Approx. body weight	Dose	Maximum daily dose (24 hours)
12 – 16 years	40 – 50 kg	1 suppository of 500 mg	4 suppositories (equivalent to 2000 mg paracetamol)
16 – 18 years	>50 kg	1 – 2 suppositories of 500 mg	6 suppositories (equivalent to 3000 mg paracetamol)

Use in adults

Arfen 500 mg suppositories are intended for rectal administration in adults (including the elderly) and children aged 12 years and over.

Administration can be repeated at intervals of 6 to 8 hours. If necessary, the interval can be at least 4 hours, not exceeding 6 daily suppositories of Arfen 500 mg.

Arfen 500 mg suppositories: 1-2 suppositories 2 to 4 times per day.

The maximum daily dose of paracetamol should not exceed 4 g/day.

If symptoms worsen or persist for more than 3 days, you should consult your doctor.

Patients with liver, kidney and Gilbert's disease should talk to the doctor for recommendation on the most appropriate dose and administration intervals.

Instructions

For rectal use.

If the suppositories softened, they can be washed in cold water before being taken out of the foil package.

If you use more Arfen than you should

If you use more Arfen than you were told to, contact a doctor or go to hospital immediately, there is a risk of liver damage even if you feel well. To prevent possible liver damage, it is important to use the antidote from your doctor as soon as possible.

The first symptoms you may experience are nausea, vomiting, increased sweating, drowsiness and malaise. You should seek medical help even if you do not have these symptoms, as you can suffer severe liver damage without realizing it. The doctor will take appropriate treatment and support measures.

If you forget to use Arfen

If you forget to use a dose, take it as soon as you remember, unless it is almost the time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Arfen

The sudden interruption of pain medications after inappropriate and prolonged administration of high doses can cause headaches, fatigue, muscle pain, irritability, among others. These symptoms disappear in a few days. Until these symptoms disappear, do not take any other painkillers or take paracetamol again, unless medically indicated.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Arfen can cause side effects, although not everybody gets them.

Stop using the medicine immediately and contact your doctor if you experience swelling of the face, particularly around the mouth (tongue and/or throat), difficulty breathing, sweating, nausea or a sudden drop in blood pressure. These symptoms may mean that you are having a severe allergic reaction, which can be life-threatening.

The following side effects may occur:

Common (may affect up to 1 in 10 people):

- Redness of the rectum mucosa.
- Slight drowsiness.
- Nausea, vomiting.

Uncommon (may affect up to 1 in 100 people):

- Dizziness (vertigo), somnolence, nervousness.
- Burning sensation in the throat.
- Diarrhea, abdominal pain (including cramps and burning), constipation.
- Headache.
- Increased sweating.
- Excessive decrease in body temperature.

Rare (may affect up to 1 in 1,000 people)

- Rash, urticaria, angioedema: swelling of the face, tongue or throat, difficulty swallowing, hives and breathing difficulties.
- Increase in some liver enzymes (serum transaminases).

Very rare (may affect up to 1 in 10,000 people):

- Disorders of blood formation (decrease in the number of platelets; decrease in the number of white blood cells, sometimes severe; general decrease in all blood elements).
- Difficulty breathing (analgesic asthma) in more sensitive people.
- Anaphylaxis, allergic reactions, including allergic dermatitis, exacerbated hypersensitivity reactions to paracetamol (Quincke's oedema, dyspnoea, sweating accesses, nausea, drop in blood pressure, even shock).
- Bronchospasm (analgesic asthma).
- Liver damage, including with alcohol abuse.
- Kidney effects, long-term use of analgesics can cause nephropathy, including papillary necrosis.

Very rare cases of serious skin reactions have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

For Malta:

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arfen

Store below 25°C. Keep the blisters in the outer carton in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Arfen contains

- The active substance is paracetamol. Each suppository contains 125mg, 250mg or 500mg paracetamol.

- The other ingredients are soya lecithin and hard fat.

What Arfen looks like and contents of the pack

Arfen suppositories are creamy, smooth homogenous, torpedo shaped.

They are presented in Aluminium – Aluminium blisters in boxes of 10, 100 or 1000 suppositories.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MEDOCHEMIE LTD, 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus

This leaflet was last revised in February 2021.