

Patient information leaflet

DISLEP 25 mg solution for injection/infusion

Levosulpiride

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

- Keep this leaflet. You may need to read it again later.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. Do not give it to anyone else. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dislep is and what it is used for
2. What you should know before you take Dislep
3. How to take Dislep
4. Possible side effects
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1. What Dislep is and what it is used for

Dislep contains the active substance levosulpiride which belongs to a group of medicines called 'psycholeptics, antipsychotics (neuroleptics)'.

It works by stimulating the motility of the stomach and intestines (gastrointestinal prokinetic).

This medicinal product is indicated for the **short-term** treatment of:

- **dyspeptic syndrome:** this syndrome, that is a set of various symptoms, referring to poor digestion, can be due to organic causes, or to lesions of digestive organs, or due to the malfunction of these organs, including those caused by poor lifestyle, without evidence of lesions in the digestive organs themselves. It is mainly linked to a difficulty in the stomach to empty itself. Some bodily disorders (such as delayed gastric emptying in the case of diabetes, or some cancers) or psychological disorders (such as anxiety and depression which can lead to alterations in gut function) can make digestion difficult. The stomach struggles to empty itself, which can lead to: pain and heartburn, loss of appetite (anorexia), flatulence, stomach swelling and tension, post-food headaches, belching, diarrhoea and constipation. Levosulpiride is prescribed to you by your doctor as you have not previously responded to other therapy;
- **vomiting** and **nausea**, symptoms caused by drugs used to treat cancer. Levosulpiride is prescribed to you by your doctor as you have not previously responded to therapy with other medicines;
- **vertigo (dizziness)**, symptoms of a disease affecting the inner ear (Mènière's disease) causing balance problems and ear disorders (such as rustling, whistling, crackling), hearing loss and nausea.

2. What you need to know before you take Dislep

Do not take Dislep

- if you are allergic to the active substance or any of the other ingredients of this medicine

- (listed in section 6);
- if you have or are suspected of having cancer of the adrenal glands (pheochromocytoma);
 - if you suffer from seizures (epilepsy);
 - if you suffer from mood disorders that can make you feel excited (manic states with hyperactivity, irritation, irritability or decreased need for sleep);
 - if you have breast cancer;
 - if you have gastrointestinal bleeding, intestinal blockage (which may be characterised by abdominal cramps, vomiting, constipation) or ulcers (lesions of the stomach/intestine wall);
 - if you are pregnant or suspect that you are pregnant or if you are breast-feeding (see "Pregnancy and breast-feeding").

Warnings and precautions

Talk to your doctor or pharmacist before taking Dislep. It is very important that you **first tell your doctor:**

- if you have a disease that reduces your ability to remember, speak and think (dementia);
- if you are elderly;
- if you have a predisposition to cerebral stroke, or have heart and/or circulatory system disorders;
- if you or any of your family members have or have suffered from a heart disease that causes an irregular heartbeat ("long QT syndrome");
- if you or someone else in your family has a history of blood clots (thrombi), as drugs like Dislep have been associated with blood clots in the veins.

Tell your doctor immediately if:

After taking this medicinal product, you experience a combination of symptoms such as fever, severe muscle stiffness, severe difficulty moving (akinesia), excessive sweating, if you have a fast heartbeat, altered blood pressure or if you lose consciousness. These are symptoms of a very serious and potentially fatal disease called "Neuroleptic Malignant Syndrome". In this case, **you must stop taking Dislep and immediately contact your doctor** who will prescribe a suitable treatment.

If you are taking anticholinergic medicines (drugs that block the action of acetylcholine, a substance involved in the transmission of nerve impulses), narcotics and analgesics (painkillers) as they can reduce the effects of Dislep (see section "Other medicines and Dislep")

Children and adolescents

Do not give this medicine to children and adolescents as no relevant data are available.

Other medicines and Dislep

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, before taking this medicine tell your doctor if you are already taking:

- medicines that act on the central nervous system used to treat psychiatric disorders, in particular neuroleptics, as combination with Dislep requires caution;
- medicines that can affect the levels of mineral elements (electrolytes) present in the blood, as they should not be taken at the same time as Dislep;
- medicines that alter the heartbeat (prolong QT), as combination with Dislep increases the risk of abnormal heartbeat (cardiac arrhythmias).
- Medicines called anticholinergics (used to counteract a substance present in our body and involved in the transmission of nerve impulses, called "acetylcholine"), medicines used for sleep (narcotics) and medicines used against pain, (analgesics) as they influence the effects of Dislep on the motility of the stomach and intestines.

Dislep with food, drink and alcohol

Do NOT drink alcohol while you are taking this medicine.

Fertility, pregnancy and lactation

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

Pregnancy

Do not take Dislep if you are pregnant or planning to become pregnant.

If you take antipsychotics ("conventional or atypical"), including Dislep during the last 3 months of pregnancy, your baby may experience the following symptoms after birth: tremors, muscle stiffness and/or weakness, drowsiness, agitation, breathing problems and food intake difficulty.

Contact your doctor if your child shows any of these symptoms.

Breast-feeding

Do not take Dislep if you are breast-feeding.

Driving vehicles and using machines

DO NOT drive vehicles, DO NOT use machines and DO NOT take part in activities that require close attention while you are taking this medicine.

High doses of this medicine can cause drowsiness, a feeling of numbness and involuntary movements. These effects can compromise your ability to drive vehicles and use machines.

Dislep 25 mg solution for injection for intramuscular and intravenous use contains less than 1 mmol (23 mg) of sodium per dose, i.e. it is practically 'sodium-free'.

3. How to take Dislep

Always take this medicine exactly as your doctor has told you. If in doubt, talk to your doctor or pharmacist.

You should always take the exact dose that your doctor has prescribed for you. The recommended doses are:

Adults

If you have **nausea and vomiting**, you may have difficulty keeping down levosulpiride tablets or oral solution. In this case, your doctor will prescribe the solution for injection until your symptoms become milder.

The recommended dose is: 1 ampoule 2 or 3 times per day, as prescribed. The ampoule can be injected either directly into a vein (intravenous) or into a muscle (intramuscular) by an authorised health professional.

You can then continue with oral therapy (with levosulpiride tablets or oral drops) for about 10 - 15 days.

If the doctor prescribes a repeat course of therapy for another 2 or 3 weeks, there will always be an interruption period of at least 8 - 10 days between one course of treatment and the next.

Treatment of vomiting caused by anticancer medicines

If the vomiting is caused by some anticancer medicines (cisplatin, anthracyclines), you may be given 1-2 ampoules intravenously (through a vein) slowly or by infusion with drip, 30 minutes before or while taking the anticancer medicine. The same dose can be repeated 30 minutes after taking the anticancer medicine.

Use in the elderly

If you are elderly, your doctor will carefully establish the dosage and evaluate a possible reduction in the dosages indicated above.

Use in children and adolescents

This medicine should not be taken by children and adolescents as no relevant data are available.

If you take more Dislep than you should

If you take more than the prescribed dose of Levosulpiride, **notify your doctor immediately or go to the nearest hospital**. Take this patient information leaflet with you.

An overdose can cause tremors, difficulty and slowness of movement (extrapyramidal disorders) or sleep disturbances.

If you forget to take Dislep

Do not take a double dose to make up for the forgotten dose.

If you have any questions about this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects have also been observed with the use of other medicines of the same class and/or with prolonged administration:

Rare (may affect up to 1 person per 1,000):

- alterations in the heartbeat (prolongation of the QT interval, ventricular arrhythmias such as torsade de pointes, ventricular tachycardia, ventricular fibrillation), cardiac arrest.

Very rare (may affect up to 1 person per 10,000):

- somnolence, Parkinsonism (symptoms similar to those present in Parkinson's disease such as, for example, tremors, difficulty and slowing of movement, stiffness and postural instability); involuntary muscle movements (dyskinesia); tremors; repetitive twisting movements or abnormal fixed positions (dystonia); Neuroleptic Malignant Syndrome (life-threatening reaction, symptoms include hyperpyrexia, muscle rigidity, akinesia, irregular pulse or blood pressure, sweating, tachycardia, arrhythmias, altered state of consciousness that may progress to stupor and coma). (see section "Tell your doctor immediately if").
- cases of sudden death.

Not known (frequency cannot be estimated from the available data):

- absence of menstruation in women of childbearing age (amenorrhoea), development of breasts in men (gynaecomastia), a feeling of tenderness in the breasts, spontaneous flow of milk from the breasts not associated with childbirth or breast-feeding (galactorrhoea), changes in sexual desire (libido).
- clot formation (venous thrombi), especially in the legs (symptoms include swelling, pain, redness of the leg), which can travel to the lungs and cause chest pain and breathing difficulties.
- neonatal withdrawal symptoms (see section 2 "Pregnancy and breast-feeding"), movement disorders (extrapyramidal symptoms).
- increased levels of a hormone called prolactin in the blood (hyperprolactinaemia).

Dislep is not indicated for the treatment of dementia. In the elderly with dementia, a small increase in the number of deaths has been observed for patients taking antipsychotics compared with those not taking antipsychotics.

Reporting side effects

If you experience 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: 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 Dislep

Dislep 25 mg solution for injection/infusion for intramuscular and intravenous use

Before first opening: These medicines do not require any special precautions for storage.

After dilution: Chemical and physical in-use stability has been demonstrated for 6 hours at room temperature when diluted with 0,9% sodium chloride solution or 5% glucose solution.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions

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

Do not use this 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 dispose of any medicines down the drain or in the household waste. Ask the pharmacist how to dispose of medicines that you no longer use. This will help to protect the environment.

6. Contents of the container and other information**What Dislep contains****Dislep 25 mg solution for injection/infusion for intramuscular and intravenous use**

- The active substance is levosulpiride, one 2 ml ampoule contains 25 mg of levosulpiride.
- The other ingredients are 2 N sulfuric acid, water for injections, sodium chloride.

Description of Dislep and contents of the packaging

Dislep 25 mg solution for injection/infusion for intramuscular and intravenous use is presented in a pack containing 6 glass ampoules of 2 ml each.

Marketing authorisation holder and manufacturer*Marketing Authorisation Holder*

Ferrer Internacional, S.A.
Gran Via Carlos III, 94
Barcelona – 08028
Spain

Manufacturer

Doppel Farmaceutici S.r.l.
Via Volturmo, 48 - 20089 Quinto dè Stampi - Rozzano (MI)
Italy

This patient information leaflet was updated on