SUMMARY OF PRODUCT CHARACTERISTICS FOR PHARMACEUTICAL PRODUCTS

1 NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

2.1. Strength

DISLEP (Levosulpiride) 25 mg

2.2. Pharmaceutical form

Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1. *Qualitative declaration*

- ***Drug substance:***

Levosulpiride

- ***Excipients:***

Microcrystalline cellulose
Lactose c
Sodium glycolate starch
Magnesium stearate

2.2. *Quantitative declaration*

- ***Drug substance:***

Levosulpiride	*25,0 mg*

- ***Excipients:***

Microcrystalline cellulose	*40,5 mg*
Lactose monohydrate	*25,0 mg*
Sodium glycolate starch	*8,0 mg*
Magnesium stearate	*1,5 mg*

2.3. *Salts and hydrates*

Not applicable

2.4. *Esters and pro-drugs*

Not applicable

2.5. *Oral powders for solution or suspension*

Not applicable

2.6. *Parenterals excluding powders for reconstitution*

Not applicable

2.7. *Powders for reconstitution prior to parenteral administration*

Not applicable

2.8. *Concentrates*

Not applicable

2.9. *Transdermal patches*

Not applicable

2.10. *Multidose solid or semi-solid products*

Not applicable

2.11. *Biological medicinal products*

Not applicable

2.11.1. Expression of strength

Not applicable

2.11.2. The biological origin of the active substances

Not applicable

2.11.3. Special provisions for normal immunoglobulins

Not applicable

2.11.4. Herbal pharmaceutical products

Not applicable

3 PHARMACEUTICAL FORM

Tablets

4 CLINICAL PARTICULARS

4.1.*Therapeutic indications*

It is used for the treatment of digestive disorders in which it is necessary to stimulate gastrointestinal motility after failure to respond to hygiene and dietary measures.

4.2.*Posology and method of administration*

Always take Dislep exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Dislep tablets should be swallowed whole with a sufficient amount of water; they should not be broken or chewed. Your doctor will inform you about the duration of treatment with Dislep.

4.3.*Method of administration*

The normal dose in adults is 1 tablet (25 mg of levosulpiride) every 8 hours, i.e. 3 tablets (75 mg of levosulpiride) per day taken orally, distributed in three doses, at least 20 minutes before meals. Use in children: The use of levosulpiride in children is not indicated. Use in the elderly: In elderly patients, the daily dose of Dislep will be established by the doctor according to the patient's needs.

4.4.*Contraindications*

- If you are allergic (hypersensitive) to levosulpiride or any of the other ingredients of Dislep.
- If you are epileptic or have a history of seizures or manic-depressive psychosis.
- If you have or are at risk of gastrointestinal bleeding, obstructions or perforations.
- If you have pheochromocytoma (tumour of the adrenal gland).
- If you have been diagnosed with malignant mastopathy (breast condition).
- If you are pregnant or breast-feeding.

4.5.*Special warnings and precautions for use*

o Painkillers (narcotics, analgesics).
o Anticholinergic and antidopaminergic drugs, ask your doctor if you have any questions.

4.6.*Paediatric population*
Not recommended in children under 18 years.

4.7. *Interaction with other medicinal products and others forms of interaction*
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Certain medicines may interact with Dislep. In such cases, it may be necessary to change the dose or stop the treatment with one of these medicines.

4.8. *Additional information on special populations*
Use in the elderly: In elderly patients, the daily dose of Dislep will be established by the doctor according to the patient's needs.

4.9. *Fertility, pregnancy and lactation*

i. *General principles*
Ask your doctor or pharmacist for advice before taking any medicine. This medicine should not be used during pregnancy or breast-feeding.

ii. *Women of childbearing potential / Contraception in males and females*
This medicine should not be used during pregnancy or breast-feeding.

iii. *Pregnancy*
This medicine should not be used during pregnancy.

iv. *Breastfeeding*
This medicine should not be used during breast-feeding..

v. *Fertility*
This medicine should not be used during pregnancy or breast-feeding.

4.10. *Effects on ability to drive and use machines*

Levosulpiride can cause symptoms such as drowsiness, dizziness, visual disturbances and decreased ability to react. These effects and the digestive disorder itself may hamper your ability to drive or operate machines. Therefore, do not drive or operate machines or do other activities that require special attention until your doctor assesses you response to this medication.

4.11. *Undesirable effects*

a) *Summary of the safety profile*

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

Very common (at least 1 in 10 patients): hoarseness, abdominal cramps, weight gain, hypersalivation (increase in saliva secretion), insomnia, constipation, vertigo and/or fatigue.
Common (at least 1 in 100 patients) drowsiness, sedation, breast swelling and tenderness, menstrual disorders, galactorrhoea (nipple discharge), gynaecomastia (increased breast size).
If you consider that any of the side effects is serious or if you notice any possible side effect not listed in this leaflet, tell your doctor or pharmacist.

b) *Tabulated list of adverse reactions*

Very common	***Common***
Hoarseness	*Drowsiness*
Abdominal Cramps	*Sedation*
Weight Gain	*Breast Swelling And Tenderness*
Hypersalivation	*Menstrual Disorders*
Insomnia	*Galactorrhea*
Constipation	*Gynecomastia*
Vertigo	
Fatigue	

c) *Description of selected adverse reactions*

- *Hoarseness: the quality of a person's voice when it sounds rough.*
- *Abdominal cramps: a sudden painful tightening in the abdominal.*
- *Hypersalivation: Increase In Saliva Secretion*
- *Insomnia: the condition of being unable to sleep, over a period of time.*

- *Constipation: a condition which makes someone unable to empty their bowels as often as they should.*
- *Vertigo: a feeling of spinning around and being unable to balance, often caused by looking down from a heigh.*
- *Fatigue: extreme tiredness.*
- *Drowsiness: a tired state, between sleeping and being awake.*
- *Sedation: a state of calm or sleep produced by a sedative drug.*
- *Breast Swelling And Tenderness*
- *Menstrual Disorders*
- *Gynecomastia: increased breast size.*
- *Galactorrhea: Spontaneous flow of milk from the breast, unassociated with childbirth or nursing.*

d) Paediatric population

The use of levosulpiride in children is not indicated.

e) Other special populations

In elderly patients, the daily dose of Dislep will be established by the doctor according to the patient's needs.

4.12. Overdose

The symptoms of Dislep overdose are mainly drowsiness and tremors. If this occurs, you should contact your doctor.

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Biochemical, pharmacological and clinical data obtained with the pair of isomers of sulpiride indicate that this drug antidopaminergic activity, both at central and at peripheral level, is due to levogyrous enantiomer.

5.2. Pharmacokinetic properties

Following levosulpiride administration by mouth at a dose of 50 mg, plasma concentration peak was reached within 3 hours after administration and was found to be 94.183 ng/ml, on average. Levosulpiride elimination half-life, when calculated following administration of a dose of 50 mg intravenously, was 4.305 hours.

This drug is mainly excreted in the urines.

5.3. Preclinical safety data

Acute toxicity values expressed as DL50 after oral administration in mice, rats and rabbits were equal to 2450 mg/Kg, 2600 mg/Kg and greater than 1500 mg/Kg, respectively. DL50 values recorded after intraperitoneal administration to mice were equivalent to 210 mg/Kg. Following drug administration intraperitoneally and intravenously to rats, DL50 values were 270 mg/Kg and 53 mg/Kg respectively. When drug was administered intravenously to rabbits, DL50 values were 42 mg/Kg.

Subacute toxicity tests were carried out by administering DISLEP active ingredient to rats, rabbits and dogs for 12-13 weeks on a daily basis. No toxic symptoms were observed at a dose of 25 mg/Kg, administered subcutaneously, and at a dose of 300 mg/Kg, given by mouth, to rats. No toxic symptom was detected at a dose of 250 mg/Kg, given by mouth and of 12.5 mg/Kg, administered i.m. to rabbits, and at a dose of 50 and 100 mg/Kg given by mouth to dogs.

Chronic toxicity tests were very well tolerated, following DISLEP administration for 180 to 190 days, at a dose of 100 mg/Kg given by mouth and of 20 mg/Kg, injected subcutaneously to rats, and at a dose of 10 mg/Kg, given i.m. to rabbits and of 20 mg/Kg, orally administered to dogs.
Studies carried out on rats and mice receiving DISLEP at a dose level that was much greater than that prescribed for humans, showed that Levosulpiride has no carcinogenic property.

Studies on rats and rabbits demonstrated that Levosulpiride is not teratogenetic.

In vitro trials ruled out that Levosulpiride may have mutagenic properties.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium glycolate starch, microcrystalline cellulose, lactose monohydrate, magnesium stearate.

6.2. Incompatibilities

No data are known on this subject.

6.3. Shelf life

5 years

6.4. Special precautions for storage

The drug product does not require any special storage conditions.

6.5. Nature and contents of container

Blister of 20 tablets of 25 mg (in aluminum/PVC/PVDC).

6.6. Special precautions for disposal and other handling

Store below 30º

7 MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorisation Holder:

FERRER INTERNACIONAL, S.A.

Gran Vía Carlos III, 94

08028-BARCELONA (Spain)

8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

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10 DATE OF REVISION OF THE TEXT

April 2021