DÉBRIDAT

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DÉBRIDAT

(Trimebutine maleate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Trimebutine maleate: 100 mg per tablet.

Excipient: lactose monohydrate, pre-gelatinized corn starch, hypromellose, sodium starch glycollate, tartaric acid, anhydrous colloidal silica, magnesium stearate, macrogol 4000, coloring agent: titanium dioxide, purified water q.s. 1 film-coated tablet.

PHARMACEUTICAL FORM

Film-coated tablets (white).

THERAPEUTIC INDICATIONS

Gastroenterology:

Polymorphous symptoms of the gastro-intestinal tract, grouped under the irritable bowel syndrome entity or functional digestive disorders, in particular abdominal pain and cramps, spasms, flatulence, diarrhea and/or constipation.

POSOLOGY AND METHOD OF ADMINISTRATION

Follow the doctor's prescription.

For reference: Adults: 1 or 2 tablets 3 times a day.

CONTRAINDICATIONS – DRUG INTERACTIONS

None.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

None.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy:

Studies in animals have not revealed any teratogenic effect. There are no adequate and well controlled studies of trimebutine in pregnant women. There was no evidence of teratogenicity or other adverse developmental effects when trimebutine was administered to pregnant rats and rabbits. Trimebutine should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the patient and fetus.

Lactation:

Safety for use in lactation has not been established.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effect of trimebutine on the ability to drive or use machinery has not been systematically evaluated.

UNDESIRABLE EFFECTS

The following Adverse Drug Reactions (ADRs) have been reported in patients receiving trimebutine.

MedDRA[#] System Organ Class	Frequency	Adverse Drug Reaction
Immune system disorders	Not Known	Hypersensitivity*[†]
Nervous system disorders	Uncommon	Pre-syncope/Syncope**
Skin and subcutaneous tissue disorders	Uncommon	Rash
	Not Known	Severe skin reactions including Acute generalized exanthematous pustulosis*, Erythema multiforme*, Toxic skin eruption*, Dermatitis exfoliative*, and Contact dermatitis*; Dermatitis*, Erythema*, Pruritus*, and Urticaria*

CIOMS III categories: Very Common ≥1/10 (≥10%), Common ≥1/100 to <1/10 (≥1% and <10%), Uncommon ≥1/1000 to <1/100 (≥0.1% and <1%), Rare ≥1/10,000 to <1/1000 (≥0.01% and <0.1%), Very Rare <1/10,000 (<0.01%), Not Known (cannot be estimated from the available data).

[#]MedDRA version 15.
*ADR identified post-marketing.
**Observed primarily with the injectable formulation.
[†]Drug hypersensitivities reported in the post-marketing setting have mainly involved skin (e.g., contact dermatitis, dermatitis, pruritus, urticaria).

OVERDOSE
In the event of overdose, symptomatic treatment should be implemented.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Gastrointestinal motility modifier. Peripheral enkephalinergic agonist.

Trimebutine stimulates intestinal motility (triggering phase-III waves propagated by the migrating motor complex) and inhibits it in the event of prior stimulation.

Pharmacokinetic properties
Peak blood levels of trimebutine after oral administration of tablets were obtained after 1 to 2 hours.

Rapid elimination of trimebutine after oral administration of tablets was mainly in the urine, on average 70% in 24 hours.

Preclinical safety data
Studies in animals have not revealed any teratogenic effect of trimebutine (see FERTILITY, PREGNANCY AND LACTATION).

STORAGE
Do not exceed the expiry date shown on the folding carton. Store below 30°C.

HOW SUPPLIED
Box of 30 film-coated tablets.

PRODUCT OWNER
Pfizer Inc
New York,
United States

DEBT-SIN-0125/0
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Package leaflet: Information for the patient

Debridat 100 mg Film-coated Tablets
(trimebutine maleate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Debridat is and what it is used for

Debridat's main ingredient is trimebutine. It belongs to a group of medicines that control how the stomach and intestines move. Debridat helps to normalize intestinal movement by either making it move more or less depending on what is needed.

Debridat is used to treat various symptoms of the digestive system, often seen in irritable bowel syndrome or other digestive problems. It helps with symptoms such as stomach pain, cramps, spasms, gas, diarrhea and constipation.

You should talk to a doctor if you do not feel better or if you feel worse after taking Debridat.

2. What you need to know before you take Debridat

Do not take Debridat if:
- you are allergic to trimebutine or any of the other ingredients of this medicine (listed in section 6)

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.

The effects of Debridat on pregnant or breast-feeding women are unknown. Debridat should only be taken if the potential benefit outweighs the potential risk.

Driving and using machines
There is no information on the effect of Debridat on the ability to drive or use machines. If you experience dizziness, drowsiness or tiredness while on treatment with Debridat, take special care when driving or using machines.

3. How to take Debridat

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is 1 or 2 tablets three times a day. Your doctor may adjust your dose depending on your needs.

If you take more Debridat than you should
If you accidentally take too many tablets, contact your doctor or go to the hospital immediately.

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

If you stop taking Debridat
It is recommended that you keep taking Debridat until your doctor tells you to stop, even if you start to feel better.

If you have any further questions on the use of 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.

Debridat may cause serious side effects. Stop taking Debridat and tell your doctor immediately if you experience any of the following symptoms after taking this medicine:

- Serious allergic reaction (Hypersensitivity): Symptoms include rash, itching, and difficulty breathing.
- Severe skin reactions such as Acute generalized exanthematous pustulosis (widespread pustular skin eruption), Erythema multiforme (skin and mucous membrane disorder), Toxic skin eruption, Dermatitis exfoliative (skin inflammation with peeling) and Contact dermatitis (skin inflammation): Symptoms include itchy, red patches, blisters, sores, fever, scaling and peeling of the skin.

Other side effects may include:

Uncommon (may affect up to 1 in 100 people):
- Pre-syncope/Syncope (Fainting)
- Rash (Skin eruption)

Not known (cannot be estimated from the available data):
- Dermatitis (Skin inflammation)

- Erythema (Reddening of the skin)
- Pruritus (Itching)
- Urticaria (Hives)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Debridat

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the blister or carton label 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 to protect the environment.

6. Contents of the pack and other information

What Debridat contains
The active substance is trimebutine. Each Debridat 100 mg tablet contains 100 mg of trimebutine.

The other ingredients are lactose monohydrate, pre-gelatinized corn starch, hypromellose, sodium starch glycollate, tartaric acid, anhydrous colloidal silica, magnesium stearate, macrogol 4000, coloring agent: titanium dioxide, purified water.

What Debridat looks like and contents of the pack
Debridat is a white film-coated tablet.

Debridat comes in a pack containing 30 tablets.

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