

Package leaflet: Information for the patient

Ortem™ 100mg/g ointment

Metronidazole (10% w/w)

Read all of this leaflet carefully before you start using 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 **Ortem** is and what it is used for
2. What you need to know before you use **Ortem**
3. How to use **Ortem**
4. Possible side effects
5. How to store **Ortem**
6. Contents of the pack and other information

1. What Ortem Ointment is and what it is used for

This product is an ointment that contains the active substance metronidazole. Metronidazole belongs to a group of medicines called antiprotozoal and antibacterial agents.

The ointment has been prescribed for you to treat non-healing pilonidal sinus.

2. What you need to know before you use Ortem Ointment

Do not use Ortem Ointment:

- if you are allergic to metronidazole or any of the other ingredients of this medicine (listed in section 6);

Warnings and precautions:

Talk to your doctor or pharmacist before using **Ortem Ointment** if you:

- are undergoing kidney dialysis;
- suffer from blood disorders.

Children and adolescents:

Ortem ointment is not suitable for children and adolescents under the age of 18 years because it has not been assessed in people in this age group.

Other medicines and Ortem Ointment:

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take **Ortem Ointment** with some other medicines, the effect of **Ortem Ointment** or the other medicine may be changed.

Talk to your doctor or pharmacist before using **Ortem Ointment** if you:

- are using other preparations containing metronidazole such as tablets taken by mouth;

- are taking warfarin or other 'blood thinning' products;
- are taking fluorouracil (a cancer drug);
- are taking medicines used to treat epilepsy, such as phenytoin, primidone, phenobarbital;
- are using any other topical preparations for pilonidal sinus.

Ask your doctor or pharmacist for advice before taking or using any medicine.

Ortem Ointment with alcohol:

Metronidazole taken by mouth can react with alcohol causing side-effects such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

You are therefore advised not to drink alcohol while using **Ortem Ointment**.

Pregnancy and breast-feeding:

Do not use if you are pregnant, think you may be pregnant, planning to have a baby or breastfeeding.

Driving and using machines:

No studies on the effect on the ability to drive and use machines have been performed with **Ortem Ointment**.

There have been reports of tiredness, dizziness, confusion and seeing or hearing things that are not there (hallucinations) in some individuals with metronidazole taken by mouth. If you are affected you should not drive or operate machinery.

3. How to use Ortem Ointment

Ortem Ointment is for external use only.

Always use **Ortem Ointment** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is approximately 700 mg of ointment (~70 mg metronidazole) applied once daily.

The ointment is applied following routine, gentle cleaning and drying of the wound.

The ointment is to be applied with the tip of a finger, which may be covered with a finger stall. (Finger stalls to be obtained separately from a pharmacy). The tube is gently squeezed to express ointment onto the finger in a strip approximately 2.5 centimetres in length which is then applied to the wound. This will then be covered with a sterile, dry gauze dressing, which is to be held in place with self-adhesive tape.

If you use more Ortem Ointment than you should:

If you have used more ointment than you should and feel unwell wipe away any extra ointment and talk to your doctor or pharmacist immediately.

If you forget to use Ortem Ointment:

Do not take a double dose to make up for a forgotten dose. Apply the next dose at the usual time.

If you accidentally swallow Ortem Ointment:

You should contact your doctor or pharmacist immediately.

If you have any further questions on the use of **Ortem Ointment**, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **Ortem Ointment** can cause side effects, although not everybody gets them.

Side-effects such as itching, redness or irritation of the skin, metallic taste or tingling of the extremities sometimes occur.

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

5. How to store Ortem Ointment

Keep **Ortem Ointment** out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after 'Exp'. The expiry date refers to the last day of that month.

Store below 30°C.

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 Ortem Ointment contains:

The active substance is metronidazole. One gram of ointment contains 100 mg metronidazole.

Approximately 70mg metronidazole is contained in the usual 700 mg dose of **Ortem Ointment**.

The other ingredient is:

White soft paraffin

S.L.A. Pharma (UK) Ltd

Ground Floor, Building 6, Leavesden Park, Hercules Way, Hertfordshire, WD25 7GS, UK

Tel: 01923 681 001

Fax: 01923 616 950