APPROVED IN
25-02-2013
INFARMED

Package leaflet: Information for the user

Hemofissural, association, cutaneous paste
Zinc oxide + Titanium dioxide + Tetracaine hydrochloride

Read all this leaflet carefully before you start using this medicine as it contains important information for you.
Always use this medicine exactly as described in this leaflet, or as your doctor has told you. Keep this leaflet. You may need to read it again.
- If you need clarification or advice, consult your pharmacist.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist or nurse.
- If you don't feel better or get worse, you need to see a doctor.

What is in this leaflet:

1. What is Hemofissural and what is used for

Hemofissural is a medicine that belongs to the pharmacotherapeutic group 6.7. - Anti-Hemorrhoidal and is indicated for the treatment of external and internal haemorrhoids, fissures, itching and irritations.

2. What you need to know before using Hemofissural

Do not use Hemofissural:
- if you are allergic (hypersensitivity) to the active substances (zinc oxide, titanium dioxide (E171) and tetracaine hydrochloride) or any other component of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Hemofissural.

Other medicines and Hemofissural
Tell your doctor or pharmacist if you are using, or have recently used, or if you may use other medicines.
No interaction studies have been conducted

APPROVED IN
25-02-2013
INFARMED

Pregnancy and breastfeeding
Since there are no studies in cases of pregnancy and lactation, it is advisable not to use the drug in these situations.

Hemofissural contains hydrated lanolin
This medicine contains hydrated lanolin. May cause local skin reactions (e.g. contact dermatitis).

3. How to use Hemofissural

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

Apply 1 or 2 times a day.

In the inner haemorrhoids apply with the aid of the cannula that accompanies the tube and in the outer, cracks and itchings apply directly on the affected region.

If you use more Hemofissural than you should
No cases of overdose were observed

If you forget to use Hemofissural
It's not to be considered.
Do not use a double dose to make up for a missed dose.

If you still have questions about the use of this medicine, talk to your doctor or pharmacist.

4. Possible side effects

As all medicines, this medicine may cause side effects, although they do not manifest in everyone.
Occasionally skin irritation reactions may occur, which disappear with the suspension of treatment.

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist, or nurse.

5. How to store Hemofisural

Store below 25°C.

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

APPROVED IN
25-02-2013
INFARMED

Do not use this medicine after the expiry date printed on the outer packaging after VAL.. The expiry date is the last day of the month indicated.

Do not use this medicine if you see visible signs of deterioration.

Do not dispose of any medicines down the drain 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 package and other information

What Hemofissural composition is
- The active substances are: zinc oxide, titanium dioxide (E171) and tetracaine hydrochloride. One gram of skin paste contains 85 mg zinc oxide, 30 mg titanium dioxide (E171) and 10 mg tetracaine hydrochloride.
- The other components are: hamamelis extract, hydrated lanolin, liquid paraffin, and purified water.

What Hemofissural looks like and contents of the pack

Hemofissural is presented in the form of cutaneous paste packed in aluminium tube.
Each tube contains 20 g of cutaneous paste, packed in a printed cardboard box.

The package contains a cannula for application of the cutaneous paste.

Marketing Authorization Holder

Baldacci - Portugal, S.A.
Rua Cândido de Figueiredo, 84-B
1549-005 Lisboa
Portugal
Phone: 217783031
Fax: 217785457
E-mail: medico@baldacci.pt

Manufacturer

Baldacci – Portugal, S.A.
Av. Santa Iria de Azóia, Bloco B/C
2695-381 Santa Iria de Azóia
Portugal

This leaflet was last revised in February 2013