Package leaflet: Information for the patient

Phloroglucinol ELC 80 mg orodispersible tablets
phloroglucinol dihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Phloroglucinol ELC is and what it is used for

Phloroglucinol ELC belongs to a group of medicines known as antispasmodic. It acts against spasms (contractions).

This medicinal product is indicated for the treatment of spasmodic pain of the intestines, the biliary tract, the bladder and the uterus.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Phloroglucinol ELC

Do not take Phloroglucinol ELC:
- if you are allergic to phloroglucinol dihydrate or any of the other ingredients of this Medicine (listed in section 6).
- if you are suffering from phenylketonuria (hereditary disease detected at birth), due to the presence of aspartame.

If in doubt, ask the advice of your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Phloroglucinol ELC.

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

Avoid combining Phloroglucinol ELC with major analgesics(medicines used to relieve pain) such as morphine or morphine derivatives as they cause spasms.

Pregnancy and breast-feeding
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.

Take Phloroglucinol ELC during pregnancy only if your doctor has advised you to do so.

Do not take this medicine if you are breast-feeding.

Driving and using machines
Phloroglucinol ELC has no or negligible influence on the ability to drive and use machines.

Phloroglucinol ELC contain lactose monohydrate and aspartame (E951)
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Phloroglucinol ELC contains 2 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly (see section Do not take Phloroglucinol ELC).

3. How to take Phloroglucinol ELC

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. The active substance is a symptomatic treatment. The duration of the treatment may vary, based on the indication. In case of persistence of symptoms, talk to your doctor.

The recommended dose is:

Adults: 2 tablets, to be taken when the pain occurs. to be repeated if there are severe spasms, with a minimum interval of 2 hours between each dose without exceeding 6 tablets per 24 hours.

Use in children over 2 years: 1 tablet to be taken when the pain occurs, to be repeated if there are severe spasms with a minimum interval of 2 hours between the previous dose without exceeding 2 tablets per 24 hours.

Method of administration
Adults: Dissolve the tablets under the tongue for a fast effect or dissolve in a glass of water.
Children: Dissolve the tablets in a glass of water. The reconstituted solution should be drunk immediately.

If you take more Phloroglucinol ELC than you should
If you accidentally take too many tablets, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take the pack with you to show which medicine you have swallowed.

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.

An allergic reaction may occur in some cases.

You will recognise the signs of an allergic reaction by:

- pimples or redness of the skin and itching,
- a sudden swelling of the face and neck (Quincke's oedema),
- or sudden faintness due to a sharp drop in blood pressure (anaphylactic shock).

In an unknown frequency of cases, there may be:

- an extensive red, squamous (scaly) eruption, with lumps under the skin and blisters, along with fever when treatment starts (generalised acute exanthematous pustulosis).

Should you develop these symptoms stop using this medicinal product and contact your family physician or immediately consult a doctor.

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. You can also report side effects directly via ADR Reporting Website: 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 Phloroglucinol ELC

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 pack, on the blister or container. The expiry date refers to the last day of that month.

Store below 30°C.
Blister packs: Store in the original package (blister) in order to protect from moisture.
Bottles: Keep the bottle tightly closed to protect from moisture.
Once opened, the bottle should be used within 1 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 Phloroglucinol ELCcontains
- The active substance is phloroglucinol dihydrate.
- **The other ingredients are:** lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate, aspartame (E951).

What Phloroglucinol ELC looks like and contents of the pack
This medicine is a white to off-white, round, uncoated orodispersible tablets, plain on both sides.
10, 20 or 30 tablets in (PVC/PVDC/Aluminium) blister packs.
20 tablets in container (HDPE)

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
ELC GROUP s.r.o.
Pobřežní 394/12, Karlin, 18600 Prague 8
Czech Republic

Manufacturer
FLAVINE PHARMA FRANCE
3 Voie d'Allemagne,
13127, vitrolles
France

Depo-pack S.r.l
Via Giovanni Morandi 28, Saronno,
21047,
Italy

This medicinal product is authorized in the Member States of the EEA under the following names:

Malta	Phloroglucinol ELC 80mg orodispersible tablet
France	Phloroglucinol ELC 80 mg comprime orodispersible
Italy	KILSPAX

This leaflet was last revised in 05/2024.