

PHLOROGLUCINOL Teva 80 mg orodispersible tablet

Phloroglucinol

Framed

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

You should always take this medicine carefully following the information given in this leaflet or by your doctor or pharmacist.

- Keep this leaflet. You might need to read it again.
- Contact your pharmacist for any advice or information.
- If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. See section 4.
- You must contact your doctor if you do not feel better or if you feel worse.

What does this booklet contain ?

1. What is PHLOROGLUCINOL Teva 80 mg orodispersible tablet and in which cases is it used?
2. What should I know before taking PHLOROGLUCINOL Teva 80 mg orodispersible tablet?
3. How to take PHLOROGLUCINOL TEVA 80 mg orodispersible tablet?
4. What are the possible side effects?
5. How to store PHLOROGLUCINOL TEVA 80 mg orodispersible tablet?
6. Contents of the pack and other information.

1. WHAT PHLOROGLUCINOL TEVA 80 mg, orodispersible tablet IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: ANTISPASMODIQUE MUSCULOTROPE - ATC code: A03AX12 (A: digestive system and metabolism) (G: genitourinary system).

PHLOROGLUCINOL TEVA belongs to a class of medicines called antispasmodics. It acts against spasms (contractions).

This medication is indicated for the treatment of spasmodic pain in the intestine, bile ducts, bladder and uterus.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PHLOROGLUCINOL Teva 80 mg orodispersible tablet?

Do not take PHLOROGLUCINOL Teva 80 mg orodispersible tablet:

- If you are allergic to phloroglucinol or one of the other ingredients of this medicine listed in section 6.

Warnings and Precautions

Talk to your doctor or pharmacist before taking PHLOROGLUCINOL Teva 80 mg orodispersible tablet.

Children and adolescents

Not applicable.

Other medicines and PHLOROGLUCINOL Teva 80 mg orodispersible tablet

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

PHLOROGLUCINOL TEVA 80 mg orodispersible tablet with food and drink

Not applicable.

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.

The use of this medication should only be considered during pregnancy if necessary.

The administration of this medication is not recommended in nursing women.

Driving and using machines

PHLOROGLUCINOL TEVA has no or negligible influence on the ability to drive and use machines.

PHLOROGLUCINOL TEVA 80 mg orodispersible tablet contains aspartame and lactose.

This medicine contains 2.00 mg of aspartame per tablet. Aspartame contains a source of phenylalanine. May be dangerous for people with phenylketonuria (PKU), a rare genetic disorder characterized by the build-up of phenylalanine that cannot be eliminated properly.

This medicine contains lactose. If your doctor has informed you of an intolerance to certain sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE PHLOROGLUCINOL TEVA 80 mg orodispersible tablet?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

Phloroglucinol Teva is symptomatic treatment. The duration of treatment is variable depending on the indication. If the symptoms persist, consult your doctor.

Dosage

In adults

Take 2 tablets at the time of the attack. Repeat in case of severe spasms, respecting a minimum interval of 2 hours between each dose without exceeding 6 tablets per 24 hours.

Use in children

In children over 2 years old, take 1 tablet at the time of the attack. Repeat in case of severe spasms, respecting a minimum interval of 2 hours between each dose without exceeding 2 tablets per 24 hours.

Method and route of administration

Oral route.

In adults: the tablets should be allowed to dissolve under the tongue for a rapid effect or to dissolve in a glass of water before ingestion.

In children: the tablets should be dissolved in a glass of water.

If you take more PHLOROGLUCINOL TEVA 80 mg, orodispersible tablet than you should

Immediately consult your doctor or pharmacist.

If you forget to take PHLOROGLUCINOL Teva 80 mg orodispersible tablet

Do not take a double dose to make up for the dose you forgot to take.

If you stop taking PHLOROGLUCINOL Teva 80 mg orodispersible tablet

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

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

In some cases an allergy can occur.

You will recognize the signs of an allergy:

- By buttons and / or redness of the skin, itching,
- by sudden swelling of the face and neck (angioedema),
- or suddenly feeling unwell due to a drop in blood pressure (anaphylactic shock).

At unknown frequency can occur:

- A scaly red rash extent with masses under the skin and blisters with fever at treatment initiation (pustulosis Acute generalized exanthematous).

If you develop these symptoms, stop using this medicine and contact your GP or see a doctor immediately.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for Medicines and Health Products Safety (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr

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

5. HOW TO STORE PHLOROGLUCINOL Teva 80 mg orodispersible tablet?

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

Do not use this medicine after the expiry date which is stated on the carton, the blisters.

Store at a temperature not exceeding 25 ° C, away from moisture.

Do not throw away any medicine 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 PACKAGE AND OTHER INFORMATION

What PHLOROGLUCINOL TEVA 80 mg contains, orodispersible tablet

- The active substance is:

Phloroglucinol 80 mg

For an orodispersible tablet.

- The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, crospovidone, povidone K90, magnesium stearate, aspartame (E951).

What PHLOROGLUCINOL TEVA 80 mg orodispersible tablet looks like and contents of the pack

This medication is in the form of orodispersible tablets.

Box of 2, 6, 10, 12, 18, 20 or 30.

Marketing authorization holder

TEVA SANTE

100-110, ESPLANADE DU GENERAL DE GAULLE
92931 PARIS LA DEFENSE CEDEX

Marketing authorization operator

TEVA SANTE

100-110, ESPLANADE DU GENERAL DE GAULLE
92931 PARIS LA DEFENSE CEDEX

Maker

OPODEX INDUSTRIE LABORATORIES

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Or

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