

Triflusal Hard capsules

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 Qualix Pharma



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TRIFLUSAL 300MG HARD CAPSULES
**PLATELET AGGREGATION INHIBITOR
(ANTITHROMBOTIC)**
LICENSE AND COMMERCIAL TERMS


PRODUCT: TRIFLUSAL
300MG
HARD CAPSULES



PACK SIZE: 20, 30,
50, 60 CAPSULES



MANUFACTURER:
EUROPEAN
(GMPs-EU)

API

EUROPEAN
(CEP)



SHELF-LIFE: 2 YEARS



DO NOT STORE
ABOVE 30°C.

BE

BE STUDY: YES



TYPE OF AGREEMENT:
LICENSE AND SUPPLY
AGREEMENT



ERRITORIAL SCOPE:
TO BE AGREED

TM

TRADEMARK:
TO BE AGREED



LICENSE FEE:
TO BE AGREED



DOSSIER FORMAT:
EU-CTD



DOSSIER STATUS:
AVAILABLE



STABILITY:
CLIMATIC ZONE II



CERTIFICATE OF
PHARMACEUTICAL PRODUCT
(CPP): AVAILABLE

TECHNICAL INFORMATION

Approved by the European Stroke Organization, triflusal is recommended as lone therapy for the secondary prevention of atheroembolic stroke.

Triflusal appears to be equally effective with a better safety profile than acetylsalicylic acid plus dypridamole and clopidogrel alone based on double blind, randomized TACIP and TAPIRSS trials.

Triflusal is chemically related to acetylsalicylic acid (ASA) and irreversibly inhibits cyclooxygenase-1 (COX-1) in platelets. Acetylation of the active group of COX-1 prevents the formation of thromboxane-B2 in platelets. However, it is unique because it spares the arachidonic acid metabolic pathway in endothelial cells. In addition, it favours the production of nitric oxide, a vasodilator. It irreversibly inhibits the production of thromboxane-B2 in platelets by acetylating cyclooxygenase-1. Triflusal affects many other targets such as NF kappa B, which is a gene expression regulatory factor for cyclooxygenase-A and cytokines. Numerous studies comparing the efficacy and safety profile (i.e. systemic haemorrhage) between triflusal and acetylsalicylic acid has shown either no significant difference or a better efficacy and safety profile for triflusal. Triflusal has been shown to protect cerebral tissue due to its inhibition of lipid peroxidation resulting from anoxia-reoxygenation.

Triflusal has shown a better safety profile than aspirin as a result of convincing evidence of lower haemorrhagic risk.

Different reasons may explain why triflusal shows an antithrombotic effect with a lower incidence of haemorrhagic complications than aspirin. The inhibition exerted by triflusal on cyclooxygenase and subsequent release of thromboxane B2 appears to be 10 times less than that of aspirin. However, its additional mechanisms of action, such as inhibition of phosphodiesterase and of the release of nitric oxide by human neutrophils, provide triflusal with enough antithrombotic activity to inhibit platelet hyperactivity observed in pro-thrombotic states but with preservation of platelet haemostatic function.

1. WHAT TRIFLUSAL IS AND WHAT IT IS USED FOR

Triflusal belongs to a class of drugs called platelet aggregation inhibitors, which act by preventing the formation of clots (thrombi) that may obstruct blood vessels.

This medicine is used to reduce the risk of recurrence of a heart attack (myocardial infarction), stable or unstable angina pectoris (chest pains), or stroke (cerebral infarction) in adults who have previously suffered any of these conditions. Also, after coronary bypass graft.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIFLUSAL

Do not take Triflusal:

- If you are allergic to triflusal, any of the other ingredients of this medicine.
- If you are allergic to salicylates.
- If you have a stomach ulcer or a history of a complicated stomach ulcer.
- If you have any other disorder that causes bleeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Triflusal.

- If you suffer from liver or kidney failure.
- If you are at risk of bleeding, due to trauma or other pathological situations or because you are undergoing long-term treatment with non-steroidal anti-inflammatory drugs, (medicines used for treating muscle or joint pain and/or inflammation).
- If you are to have surgery. Your risk of bleeding should be assessed and if necessary, you will have to stop taking triflusal seven days before surgery.

Consult your doctor even if in the past you have ever experienced any of the above mentioned conditions.

Children and adolescents

Safety and efficacy in children under 18 years of age have not been established, therefore the use of triflusal in children is not recommended.

Other medicines and Triflusal

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

Certain medicines may interact with triflusal, in which case a dose adjustment or discontinuation of treatment may be necessary.

It is important for you to inform your doctor if you are taking any of the following medicines: non-steroidal anti-inflammatory drugs (NSAIDs), oral antidiabetics or oral anticoagulants. The effects of these medicines may be enhanced, including those of triflusal.

Triflusal with food and drink

Taking Triflusal with food decreases the chances of gastrointestinal side effects.

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.

Driving and using machines

No effects on the ability to drive or use machines have been reported.

3. HOW TO TAKE TRIFLUSAL

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

POSODOLOGY

The recommended dose is two capsules (600 mg of triflusal) daily, as a single dose or two divided doses or three capsules (900 mg of triflusal) daily, three divided doses. Do not stop taking triflusal unless instructed by your doctor.

Method of administration:

Oral use.

Take the capsule with a sufficient amount of fluid and preferably with meals.

Taking too much triflusal may cause dizziness, double vision, difficulty speaking, drowsiness, lethargy, and mild diarrhoea.

4. POSSIBLE SIDE EFFECTS

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

Very common side effects (may affect more than 1 in 10):

- Indigestion.

Common side effects (may affect up to 1 in 10 people):

- Headache.
- Abdominal pain.
- Nausea.
- Constipation.
- Vomiting.
- Flatulence.
- Anorexia.

These symptoms are usually mild and disappear in a few days even if treatment is not discontinued.

Uncommon side effects (may affect up to 1 in 100 people):

- Gastrointestinal bleeding.
- Distended abdomen.
- Diarrhoea.
- Melena (black stools).
- Rectal bleeding.
- Red blood cells in the urine (haematuria).
- Nosebleed, bruises, bleeding gums.
- Purple spots on the skin (purpura).
- Cerebral haemorrhage.
- Urinary tract infection.
- Itchy skin, skin rash.
- Confusion.
- Vertigo.
- Dizziness.
- Seizures.
- Ringing in the ears.
- Loss of hearing.
- Taste disturbance.
- High blood pressure.
- Transient ischaemic attack.
- Shortness of breath (dyspnoea).
- Upper respiratory tract infection.
- Anaemia.
- Fever.
- Influenza symptoms.

Very rare (may affect up to 1 in 10,000 people):

- Some isolated cases of allergic reaction in skin exposed to sunlight have also been reported.

5. HOW TO STORE TRIFLUSAL

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

Do not store above 30°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Triflusal looks like and contents of the pack

Triflusal 300mg hard capsules: transparent hard gelatin capsules containing a white crystalline powder

Pack size: 20, 30, 50 or 60 capsules.