

Algikey

Injectable 3%



Ketorolac tromethamine

COMPOSITION:

Each 1 ml ampoule contains:

Ketorolac tromethamine	30 mg
Alcohol	100 mg
Sodium chloride	4,35 mg
Water for injection, s.q.	1 ml

PHARMACEUTICAL FORMULATION AND PACKAGING CONTENTS:

6 ampoules of 1 ml with 30-mg of Ketorolac tromethamine.

ACTIVITY:

Analgesic belonging to non-steroidal anti-inflammatory group.

PROPRIETER AND MANUFACTURER:

INKEYSA, S.A.

C/ Juan XXIII, 15-19

08950 – ESPLUGUES DE LLOBREGAT

Barcelona - SPAIN

INDICATIONS:

Short-time treatment of moderate or severe pain.

CONTRAINDICATIONS:

- If you have ever experienced allergy to acetyl salicylic acid or other non-steroidal anti-inflammatories, you should not take Ketorolac.
- Angiodema, bronchospasm or nasal polyps.
- Peptic ulcer.
- Asthma.
- Moderate or severe renal dysfunction.
- Coagulation alterations, hemorrhagic diathesis, cerebral hemorrhage or any other blood disorder which can cause hemorrhagia.
- Concomitant administration of other NSAIDs.
- If you are following an anticoagulant therapy at complete doses.
- Concomitant treatment with probenecid, lithium salts and pentoxifyllin.
- Pregnancy, labor and lactation.
- Children under 16 years old.

PRECAUTIONS:

ALGIKEY Injectable, as it contains the excipient ethanol, may be a cause of risk in patients with hepatic disease, alcoholism, epilepsy and in pregnant women and children.

Before beginning ALGIKEY Injectable treatment, you should consult your doctor if you suffer hepatic or renal insufficiency, heart decompensation, hypertension, previous digestive or hematologic problems, or if you are over 65 years old.

INTERACTIONS:

You must inform your doctor if you are taking other analgesics or another treatment, since simultaneous taking with other medicines may make it necessary to modify the dose of one of them, specially furosemide and methotrexate.

WARNINGS:

If epigastric pain, black excrements, hemorrhage of the rectum or hemathemesis are experienced, you must stop the treatment and consult your doctor immediately.

DOSAGE:

ALGIKEY Injectable treatment must be followed under control and because of doctor recommendation.

Recommended initial dose intramuscularly or intravenously is 10 mg followed by 10-30 mg dose every 4-6 h, according to needs for controlling pain. If intense pain or very intense pain, recommended initial dose is 30 mg of Ketorolac. Daily maximum dose will not exceed 90 mg in adults and 60 mg in elderly people. Maximum treatment length will be no longer than two days.

When the response is appropriate, the doctor can order to follow the treatment using tablets, taking into account that the total daily combined dose should not be more than 90 mg in adults and 60 mg in elderly people the day the change from injectable to tablets is done. The administration of the medicine depends on the presence of painful symptoms, as soon as they disappear, medication should be stopped.

OVERDOSE:

Overdosing may provoke abdominal pain and peptic ulcer that diminish when the medicine administration is interrupted. If necessary, symptomatic treatment is recommended.

If overdosing or accidental ingestion, consult the Poison Centre.

ADVERSE REACTIONS:

The most frequent side effects are: dyspepsia, gastrointestinal pain, nausea and somnolence.

As well, allergic reactions, renal effects, possibility of hemorrhage and other gastrointestinal and central nervous system effects may occur. If you experienced one of these symptoms while following ALGIKEY treatment or another one you think it could be related with this medication, you must inform your doctor.

EXPIRY:

This medicine should not be used after the expiry date stated in the packaging.

OTHER PRESENTATIONS:

Package of 6 ampoules of 1 ml with 10 mg of Ketorolac tromethamine.

LAST REVISION OF THE TEXT:

June 2002.

**DRUGS SHOULD BE KEPT OUT OF CHILDREN'S REACH
UNDER PRESCRIPTION**

Inkeysa, s.a.

Juan XXIII, 15-19

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