

Prodex

[Dexibuprofen]

100mg/5ml Suspension
300mg & 400mg Tablets

COMPOSITION

Prodex 100mg/5ml Suspension
Each 5 ml contains:
Dexibuprofen 100 mg
Product Complies Innovator's Specs.

COMPOSITION

Prodex 300mg Tablets
Each film coated tablet contains
Dexibuprofen 300mg
Product Complies Innovator's Specs.

COMPOSITION

Prodex 400mg Tablets
Each film coated tablet contains
Dexibuprofen 400mg
Product Complies Innovator's Specs.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Dexibuprofen (= S(+)-ibuprofen) is considered to be the pharmacologically active enantiomer of racemic ibuprofen. Dexibuprofen is a non-steroidal substance with anti-inflammatory and analgesic effects. Its mechanism of action is thought to be due to inhibition of prostaglandin synthesis.

Pharmacokinetics

Dexibuprofen is absorbed primarily from the small intestine. After metabolic transformation in the liver (Hydroxylation, carboxylation), the pharmacologically inactive metabolites are completely excreted, mainly by the kidneys (90%), but also in the bile. The elimination half-life is 1.8 to 3.5 hours; the plasma protein binding is about 99%. Maximum plasma levels are reached about 2 hours after oral administration. The administration of dexibuprofen with a meal delays the time to reach maximum concentrations (From 2.1 hours after fasting conditions to 2.8 hours after non-fasting conditions) and decreases the maximum plasma concentrations (From 20.6 to 18.1 pg/ml, which is of no clinical relevance), but has no effect on the extent of absorption.

INDICATIONS

Dexibuprofen is indicated for the treatment of:

- Pain and inflammation caused by osteoarthritis.
- Acute symptomatic treatment of pain during menstrual bleeding (Primary dysmenor-rhoea).
- Mild to moderate pain, such as pain in the muscles and joints and dental pain.
- It may be used as an antipyretic to reduce fever.

CONTRA-INDICATIONS

Dexibuprofen should not be administered to:

- Patients with hypersensitivity to dexibuprofen or other non-steroidal anti-inflammatory drugs.
- Patients with active or suspected gastrointestinal ulcer or history of recurrent gastrointes- tinal ulcer.
- Patients who have gastrointestinal bleeding or other active disorders.
- Patients with active Crohn's disease or active ulcerative colitis.
- Patients with severe renal dysfunction (GFR <30ml/min).
- Patients with severely impaired hepatic function.
- Patients with hemorrhagic diathesis and other coagulation receiving anticoagulant therapy
- From the beginning of 6th month of pregnancy.

PRECAUTIONS

Symptoms or history of gastro-intestinal disease, asthma, impaired hepatic, cardiac or renal function. NSAID may mask infections or temporarily inhibit platelet aggregation. In late pregnancy, as with other NSAIDs, it should be avoided as it may cause premature closure of ductus arteriosus. Dexibuprofen should be used with caution in nursing mother.

SIDE EFFECTS:

Clinical experience has shown that the risk of undesirable effects induced by dexibuprofen is comparable to that of racemic ibuprofen. The most common adverse events are gastrointestinal in nature.

DRUG INTERACTIONS

Anticoagulants:

The effects of anticoagulants on bleeding time can be potentiated by NSAIDs. If concomitant treatment can not be avoided blood coagulation tests (INR, bleeding time) should be performed during the initiation of dexibuprofen treatment and the dosage of the anticoagulant should be adjusted if necessary. Methotrexate used of doses of

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(ڈیکس آئبوپروفین)

گولیوں / سسپشن

15mg/week or more: If NSAIDs and methotrexate are given within 24 hours of each other plasma levels of methotrexate may increase, via a reduction in its renal clearance thus increasing the potential for methotrexate toxicity. Therefore, in patients receiving high-dose treatment with methotrexate, the concomitant use of dexibuprofen is not recommended.

Lithium:

NSAIDs can increase the plasma levels of lithium, by reducing its renal clearance. The combination is not recommended. Frequent lithium monitoring should be performed. The possibility of reducing the dose of lithium should be considered. Other NSAIDs and salicylates (Acetylsalicylic acid at doses above those used for anti-thrombotic treatment, approximately 100mg/day): The concomitant use with other NSAIDs should be avoided, since simultaneous administration of different NSAIDs can increase the risk of gastrointestinal ulceration and hemorrhage.

DOSAGE & ADMINISTRATION

The dosage should be adjusted to the severity of the disorder and the complaints of the patient.
The recommended dosage is 600 to 900mg dexibuprofen daily, divided in up to two to three divided doses.
The maximum single dose is 400mg dexibuprofen.
The maximum daily dose is 1200mg dexibuprofen.

300mg TABLETS:

For osteoarthritis:

The usual dose is 300mg tablet 2 to 3 times a day. For acute symptoms, the acute symptoms, the dose may be increased to 300mg tablet 4 times a day.

For primary dysmenorrhoea:

The usual dose is 300mg tablet 2 to 3 times a day.

For mild to moderate pain:

The usual dose is 300mg times a day. If needed the dose may be increased to 300mg tablet 4 times a day.

400mg TABLETS:

For osteoarthritis:

The usual dose is 400mg tablet 2 times a day. For dose may be increased to 400mg tablet 4 times a day.

For primary dysmenorrhoea:

The usual dose is 400mg tablet 2 times a day.

For mild to moderate pain:

The usual dose is 300mg times a day. If tablet 2 needed the dose may be increased to 400mg tablet 3 times a day.

Hepatic dysfunction:

Patients with mild to moderate hepatic dysfunction should start therapy at reduced doses and be closely monitored. Dexibuprofen should not be used in patients with severe hepatic dysfunction.

Renal dysfunction:

The initial dosage should be reduced in patients with mild to moderate impaired renal function. Dexibuprofen should not be used in patients with severe renal dysfunction.

100mg/5ml SUSPENSION

Children and adolescents:

10 to 15mg/kg daily in 2 to 4 divided doses or as directed by the physician.

PRESENTATION

PRODEX 100 mg/5 ml suspension in 60ml bottle.

PRODEX 400 mg tablets in blister pack of 30's.

PRODEX 300 mg tablets in blister pack of 30's

STORAGE CONDITIONS AND INSTRUCTIONS

- Store below 30° C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

غوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

- دوا کو 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

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