29-12-2022
3rd Copy

For Suspension
Change in pack size
60 to 90ml

210mm

Tercica® Tablets / Suspension
(Dexibuprofen)

COMPOSITION

Tercica® 200mg Tablets
Each film coated tablet contains:
Dexibuprofen MS 200mg

Tercica® 300mg Tablets
Each film coated tablet contains:
Dexibuprofen MS 300mg

Tercica® 400mg Tablets
Each film coated tablet contains:
Dexibuprofen MS 400mg

Tercica® 100mg/5ml Suspension
Each 5ml contains:
Dexibuprofen MS 100mg

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 18.1µg/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 dysmenorrhoea).
- 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.

CONTRAINDICATIONS:
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 gastrointestinal ulcer.
- Patients who have gastrointestinal bleeding or other active bleedings or bleeding 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 haemorrhagic diathesis and other coagulation disorders, or patients receiving anticoagulant therapy.
- From the beginning of 6th month of pregnancy.

PRECAUTIONS: Symptoms or history of gastrointestinal 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 mothers.

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 at doses of 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 three single doses.
The maximum single dose is 400mg dexibuprofen.
The maximum daily dose is 1200mg dexibuprofen.

200mg Tablets:

For osteoarthritis: The usual dose is 200mg tablet 3 times a day or two 200mg tablets 2 times a day. For acute symptoms, the dose may be increased to 200mg tablet 6 times a day.

For primary dysmenorrhoea: The usual dose is 200mg tablet 3 times a day or two 200mg tablets 2 times a day.

For mild to moderate pain: The usual dose is 200mg tablet 3 times a day. If needed the dose may be increased to 200mg tablet 6 times a day.

300mg Tablets:

For osteoarthritis: The usual dose is 300mg tablet 2 to 3 times a day. For 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 tablet 2 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 acute symptoms, the dose may be increased to400mg 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 400mg tablet 2 times a day. If 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

SHELF LIFE
See expiry on the pack.

AVAILABILITY
Tercica® 200mg tablets in a pack of 30's
Tercica® 300mg tablets in a pack of 30's
Tercica® 400mg tablets in a pack of 30's
Tercica® 100mg/5ml suspension in pack of 90ml & 120ml

INSTRUCTIONS
Dosage: As directed by the physician.
Keep out of reach of children.
For Tablets: Avoid exposure to heat, light and humidity. Store between 15 to 30°C.
For Suspension: Do not store over 30°C, and protect from heat, light and freezing.
Improper storage may deteriorate the medicine.

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com
Mfg. Lic. No. 000072

ٹرسیکا ٹیبلٹ/سسپینشن
(ڈیکسآئبوپروفن)

ہدایات:
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
بچوں کی پہنچ سے دور رکھیں۔
برائے ٹیبلٹ: دوا کو گرمی، روشنی اور نمی سے محفوظ
۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں۔
برائے سسپینشن: دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،
گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں۔
ورنہ دوا خراب ہو جائیگی۔

150mm