SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

TRANSACT® Transdermal Therapeutic System

COMPOSITION

Each patch contains 40 mg flurbiprofen.

PHARMACOLOGICAL CLASSIFICATION

A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION

TransAct contains flurbiprofen, chemically described as 2 - (2-fluoro-4-biphenylyl) propionic acid, a non-steroidal anti-inflammatory agent which has anti-inflammatory, analgesic and anti-pyretic properties. Flurbiprofen is an inhibitor of prostaglandin synthetase enzymes.

Application of TransAct results in the diffusion of the flurbiprofen molecule through the skin and subcutaneous fat to the deeper tissues.

Although the bioavailability from the formulation is slow (approximately 2%), concentrations of flurbiprofen in the deeper tissues around joints are similar to those seen after conventional oral dosing.

Concentrations of flurbiprofen in the blood are, however, much lower, with maximal plasma levels of 38,5 ng/ml observed at 13,8 hours after a single 14-hour application.

Plasma concentrations of flurbiprofen continue to rise on repeated application to reach steady state in about 1-2 weeks.

However, steady state plasma levels (about 100- 200 ng/ml) remain very much lower than after oral therapy. After removal, plasma flurbiprofen levels decline more slowly than after oral administration due to continued distribution from the tissues, and fall to undetectable levels within 48 hours.

In blood, flurbiprofen is highly protein bound (>99%).

Elimination of flurbiprofen is via the kidney, mostly in the form of metabolites. The metabolic profile following topical administration is similar to that after oral dosing; hydroxyflurbiprofen is the principle metabolite.

INDICATIONS

TransAct is indicated for the symptomatic relief of localised pain and inflammation associated with soft tissue rheumatism, trauma and osteoarthritis.

CONTRA-INDICATIONS

TransAct is contra-indicated in the patients who have previously shown a hypersensitivity to flurbiprofen. TransAct should not be applied to the skin of patients who have experienced bronchospasm, anaphylactoid reactions, angioedema or other hypersensitivity type reactions related to the use of aspirin or of other non- steroidal anti-inflammatory agents.

It should not be applied to broken or fragile skin, or to sites affected by dermatoses or infection. Systemic absorption is increased if TansAct is applied to damaged skin.

WARNINGS

Keep out of reach of children.

Safety and efficacy in the children have not been established and therefore TransAct is not indicated for use in children under 12 years of age.

Insufficient safety data are available for continuous use for more than 4 weeks, therefore TransAct is not indicated for use for more than 4 weeks.

TransAct should be used with caution in patients with a history of non-allergic asthma.

The safety of TransAct during pregnancy and lactation has not been established.

DOSAGE AND DIRECTION FOR USE

TransAct is for external use only.

The affected area should be cleaned and only one patch should be applied at time to a single site. A fresh patch is applied every 12 hours.

The backing film is removed by rubbing a corner between the fingers and the adhesive side applied to the skin. When applying TransAct to more mobile joints such as the knee or elbow, bend the joint before applying and stretch the patch around the joint.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

The most common reactions are local and include itching, redness, numbness and tingling at the site of application. If local irritation develops, treatment with TransAct should be discontinued.

Where TransAct is applied over a prolonged period of time, the possibility of systemic side-effects cannot be completely excluded.

Side effects as experienced with systemically absorbed flurbiprofen include the following:

Epigastric pain, eructation, nausea and diarrhoea, headache or slight dizziness. If they persist or are troublesome, the preparation must be discontinued.

There have been reports of skin rash, peripheral oedema, gastro-intestinal ulceration or haemorrhage, hypersensitivity reactions (e.g. bronchospasm, anaphylactic/ anaphylactoid

systemic reactions), elevated transaminase levels, jaundice, hepatitis, renal failure and nephrotic syndrome.

Isolated cases of dyshaemopoiesis (leucopenia, thrombocytopenia, aplastic anaemia) and of erythema multiforme have been observed.

During prolonged treatment with TransAct, blood counts and monitoring of hepatic and renal function are indicated as precautionary measures.

Precautions

Caution should be exercised when commencing treatment with TransAct in patients with a history of peptic ulceratin, gastrointestinal haemorrhage, ulcerative colitis, cardiac decompensation and hypertension.

As it has been shown that flurbiprofen given systemically may prolong bleeding time, TransAct should not be used with caution by patients with a potential for abnormal bleeding.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Overdosing is unlikely to occur because of the nature of the formulation. There is no specific antidote to flurbiprofen.

IDENTIFICATION

A 10 x 14 cm patch consisting of an un-woven polyester backing spread evenly with a white to pale yellow ointment and covered by a peel-off liner. The ointment has an odour of peppermint.

PRESENTATION

Carton containing either 1 or 2 resealable laminated sachets. Each sachet contains 5 TransAct patches.

STORAGE INSTRUTIONS

Store at or below 25℃. Keep out of reach of children. Reseal sachet after use. The product must not be used longer than one month after opening the sachet.

REGISTRATION NUMBER

28/3.1/0268

NAME AND BUSINESS ADRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

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