Product Information

Mersyndol

NAME OF THE MEDICINE

Mersyndol

DESCRIPTION

Mersyndol contains paracetamol 450 mg, codeine phosphate 9.75 mg, doxylamine succinate 5 mg. Paracetamol is an odourless, crystalline powder or crystals with a bitter taste. Codeine phosphate is an odourless, crystalline powder or small colourless crystals with a bitter taste. Doxylamine succinate is a powder with a characteristic odour.

Mersyndol also contains sodium starch glycollate, purified talc, magnesium stearate, microcrystalline cellulose, quinoline yellow CI 47005 and sunset yellow FCF 15985.

Mersyndol is aspirin-free.

PHARMACOLOGY

Paracetamol is an effective and fast-acting analgesic which relieves mild to moderate pain. It is rapidly absorbed from the gastrointestinal tract with peak plasma levels usually reached half to one hour after oral administration. It also reduces fever by a direct effect on the heat-regulating centres to increase dissipation of body heat.

Codeine phosphate is an effective oral analgesic which provides relief from mild to moderate pain. It is also well absorbed from the gastrointestinal tract after oral administration. The abuse potential of codeine is lower than that of other opiates.

Doxylamine succinate belongs to the ethanolamine class of antihistamines with sedative properties. Its calmative effect is useful in enhancing the effects of analgesics.

INDICATIONS

Symptomatic relief of moderate to severe pain including headache, toothache, backache or pain associated with trauma or surgery.

The calmative properties of Mersyndol may be especially useful in the treatment of tension headache, migraine and period pain and the antipyretic properties may be useful in controlling fever.

CONTRAINDICATIONS

Known hypersensitivity to paracetamol, codeine or doxylamine succinate; patients with pre-existing respiratory depression. Patients with glucose-6-phosphate-dehydrogenase deficiency.

PRECAUTIONS

Mersyndol should be used with caution in severe hepatic or renal dysfunction.

Both doxylamine succinate and codeine may cause drowsiness in some patients, thus patients should be cautioned about operating vehicles or machinery or engaging in activities which require them to be fully alert. Avoid alcohol.

Products containing codeine should not be given for prolonged periods as they may be habit-forming.

This medication may be dangerous when used in large amounts or for long periods. Hepatotoxicity may develop following a dose of 10 g of paracetamol and hepatic failure is known to occur occasionally with the long term use of paracetamol.

Patients with known analgesic intolerance or known bronchial asthma must only use Mersyndol after having consulted a physician (hypersensitivity reactions including bronchospasm are possible).

Use in Pregnancy

Category A. There have been no observations of an increase in the frequency of malformations or other direct or indirect harmful effects on the foetus in pregnant women and women of child-bearing age who have taken those drugs found in Mersyndol.

Use in Lactation

There are no data available on the use of Mersyndol during lactation. Paracetamol does pass into the breast milk and use of this product by nursing mothers should only be following the thorough assessment of possible risks and benefits.

Interactions with other drugs

Patients receiving other CNS depressants eg. hypnotics, sedatives, tranquillisers, including alcohol, concomitantly may exhibit an additive CNS depression. Barbiturates and other antiepileptics (including phenytoin and carbamazepine), rifampicin and prolonged alcohol ingestion may increase the metabolism of paracetamol to metabolites toxic to the liver.

Paracetamol may increase the risk of bleeding in patients taking warfarin and other coumarin derivatives, particularly if paracetamol is taken in high doses or for several days. Patients taking paracetamol and coumarin derivatives should be monitored for appropriate coagulation and bleeding complications.

Paracetamol may considerably slow down the excretion of chloramphenicol, entailing the risk of increased toxicity. When used concurrently with zidovudine, an increased tendency for neutropenia may develop. Combination of Mersyndol and zidovudine should be avoided.

Concurrent intake of drugs, which delay gastric emptying, such as propantheline, may slow down the uptake of paracetamol, thereby retarding its onset of action. Conversely, drugs, which accelerate gastric emptying, such as metoclopramide, may accelerate the uptake of paracetamol and its onset of action.

ADVERSE EFFECTS

Side-effects with Mersyndol are infrequent. However, among those reported are: anorexia, drowsiness, depression, dizziness, sweating, angioneurotic oedema, difficulty in breathing, drop in blood pressure, gastrointestinal discomfort such as nausea and diarrhoea, dry mouth and, on rare occasions, rash.

Paracetamol may occasionally cause skin reactions and isolated cases of agranulocytosis and thrombocytopaenic purpura have been reported. Changes in blood picture (rarely thrombocytopenia, leukopenia, and, in isolated cases, agranulocytosis and pancytopenia) may occur.

Bronchospasm may be triggered in patients having a tendency of analgesic asthma.

Doxylamine succinate may cause drowsiness in some individuals. Constipation and pancreatitis may occur in association with codeine.

DOSAGE AND ADMINISTRATION

<u>Adults and children 12 years of age and older</u>

One or two tablets every 4 to 6 hours as needed for relief. Do not exceed 8 tablets in 24-hour period. Not recommended to be used for long periods.

Children under 12 years

Not recommended.

OVERDOSAGE

It has been reported that paracetamol may produce symptoms of acute toxicity in adults, following the ingestion of more than 15g. Hepatotoxicity may develop after the ingestion of a single dose of 10 to 15g (200 to 250 mg/kg) and a dose of more than 25g is potentially fatal. Patients may be asymptomatic for several days following ingestion of large doses of paracetamol and laboratory evidence of hepatotoxicity may be delayed for up to one week. Non-fatal hepatic damage is usually reversible. The antidote, N-acetylcysteine, should be administered as early as possible.

In an evaluation of codeine intoxication in children, symptoms ranked by decreasing order of frequency included sedation, rash, miosis, vomiting, itching, ataxia and swelling of the skin. Respiratory failure may occur. Blood concentrations of codeine ranged from 1.4 to 5.6 g/mL in eight adults whose deaths were attributed primarily to codeine overdosage.

Reactions associated with doxylamine overdosage may vary from CNS depression to stimulation. Stimulation is particularly likely in children; insomnia, nervousness, euphoria, irritability, tremors, nightmares, hallucinations and convulsions can occur. Atropine-like signs and symptoms such as dry mouth, fixed, dilated pupils, flushing and gastrointestinal symptoms may also occur.

Contact the Poisons Information Centre for advice on management of overdose.

PRESENTATION AND STORAGE CONDITIONS

Mersyndol is available as 20 tablets or caplets, each containing paracetamol 450 mg, codeine phosphate 9.75 mg and doxylamine succinate 5 mg.

The tablets are yellow, marked with 'M' inside two concentric circles on one side and 'Mersyndol 008' and a breakline on the reverse

The caplets are yellow, capsule-shaped tablets with 'Mersyndol' on one side and a breakline on the other.

Storage Conditions: store below 30 ^{o}C

NAME AND ADDRESS OF THE SPONSOR

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

POISON SCHEDULE OF THE MEDICINE

S3 Pharmacist Only Medicine

DATE OF APPROVAL

Date of TGA approval: August 30 1996

Date of most recent amendment: November 24 2006