

DATA SHEET

Temgesic Injection

Qualitative and Quantitative Composition

Buprenorphine hydrochloride 324µg/ml, equivalent to 300µg buprenorphine base.

Pharmaceutical Form

Terminally sterilised solution for injection.

Clinical Particulars

Therapeutic Indications

As a strong analgesic for the relief of moderate to severe pain.

Posology and Method of Administration

Administration by i.m. or slow i.v. injection.

Adults and children over 12 years:

1-2ml (300-600 micrograms of buprenorphine) every 6-8 hours or as required.

Children aged under 12 years: Not currently recommended.

There is no evidence that dosage need be modified for the elderly.

Temgesic Injection may be employed in balanced anaesthetic techniques as a pre-medication at a dose of 300 micrograms i.m., or as an analgesic supplement at doses of 300 to 450 micrograms i.v.

Contra-Indications

Not to be given to patients who are known to be allergic to Temgesic or other opiates.

Special Warnings and Precautions for Use

Temgesic occasionally causes significant respiratory depression and, as with other strong centrally acting analgesics, care should be taken when treating patients with impaired respiratory function or patients who are receiving drugs which can cause respiratory depression.

Although volunteer studies have indicated that opiate antagonists may not fully reverse the effects of Temgesic, clinical experience has shown that Naloxone may be of benefit in reversing a reduced respiratory rate. Respiratory stimulants such as Doxapram are also effective. The intensity and duration may be affected in patients with impaired liver failure.

Interactions with Other Medicaments and Other Forms of Interaction

There is evidence to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, in individuals on high doses of opioids buprenorphine may precipitate abstinence effects due to its properties as a partial agonist.

Controlled human and animal studies indicate that buprenorphine has a substantially lower dependence liability than pure agonist analgesics. In patients abusing opioids in moderate doses substitution with buprenorphine may prevent withdrawal symptoms. In man limited euphorogenic effects have been observed. This has resulted in some abuse of the product and caution should be exercised when prescribing it to patients known to have, or suspected of having, problems with drug abuse.

Temgesic may cause some drowsiness which may be potentiated by other centrally acting agents, including alcohol, tranquillisers, sedatives and hypnotics. Temgesic should be used with caution in patients receiving monoamine oxidase inhibitors, although animal studies have given no evidence of interactions.

Temgesic has no known effects on diagnostic laboratory tests.

Pregnancy and Lactation

Temgesic is not recommended for use during pregnancy. Animal studies indicate that the amounts of buprenorphine excreted in milk are very low and in human use are unlikely to be of clinical significance to the baby. There is indirect evidence in animal studies to suggest that Temgesic may cause a reduction in milk flow during lactation. Although this occurred only at doses well in excess of the human dose, it should be borne in mind when treating lactating women.

Effects on Ability to Drive and Use Machines

Ambulant patients should be warned not to drive or operate machinery until they are certain they can tolerate Temgesic.

Undesirable Effects

Nausea, vomiting, dizziness, sweating and drowsiness have been reported and may be more frequent in ambulant patients. Hallucinations and other psychotomimetic effects have occurred although more rarely than with other agonists/antagonists. Elderly patients would be expected to be more susceptible to these effects. Hypotension leading to syncope may occur. Rashes, headache, urinary retention and blurring of vision have occasionally been reported. Rarely, a serious allergic reaction may occur following a single dose.

Overdose

Supportive measures should be instituted and if appropriate Naloxone or respiratory stimulants can be used. The expected symptoms of overdosage would be drowsiness, nausea and vomiting; marked miosis may occur.

Pharmacological Properties

Pharmacodynamic Properties

Buprenorphine is a strong analgesic of the partial agonist (mixed agonist/antagonist) class.

Pharmacokinetic Properties

Buprenorphine is readily available by i.v. or i.m. routes; the relative bioavailability i.m. to i.v. was 1.07. Peak plasma levels are achieved within a few minutes of i.m. administration and after 10 minutes are not significantly different from those observed after the same dose given i.v.

Preclinical Safety Data

No preclinical findings of relevance to the prescriber have been reported.

Pharmaceutical Particulars

List of Excipients

Dextrose anhydrous parenteral, hydrochloric acid and water for injections.

Incompatibilities

None stated.

Shelf Life

Five years.

Special Precautions for Storage

The product, though stable, should be kept cool and protected from light.

Nature and Contents of Container

Sealed Type I glass ampoules. Pack size: five ampoules.

Instructions for Use/Handling

Administration by i.m. or slow i.v. injection.

Legal Category

Controlled Drug

Administrative Data

Name and Address

Reckitt & Colman
289 Lincoln Road
Henderson
Auckland 1231.

Phone (09) 839 0200

Facsimile (09) 839 0202

Date of Preparation

June 9, 1999