

Vastisol

1g/1000ml
Infusion
(P a r a c e t a m o l B P)

ویسٹیسول
پیراسیٹامول - بی پی
انفیوژن
۱ گرام / ۱۰۰۰ ملی لیٹر

COMPOSITION

Each 100ml contains:

Paracetamol (BP).....1g

Product complies Innovator's specs.

DESCRIPTION

Paracetamol (acetaminophen) is a pain reliever and a fever reducer. The exact mechanism of action of is not known. It is typically used for mild to moderate pain. It is often sold in combination with other ingredients such as in many cold medications. Paracetamol is used to treat many conditions such as headache, muscle aches, arthritis, backache, toothaches, colds, and fevers. It relieves pain in mild arthritis but has no effect on the underlying inflammation and swelling of the joint.

Paracetamol is generally safe at recommended doses. Serious skin rashes may rarely occur. Too high a dose can result in liver failure. It appears to be safe during pregnancy and when breastfeeding. In those with liver disease, it may still be used but lower doses should be taken. Paracetamol is classified as a mild analgesic. It does not have

DOSAGE & ADMINISTRATION

Paracetamol solution is administered as a 15-minute intravenous infusion.

| Patient weight | Dose per administration | Volume per administration | Maximum volume of paracetamol, solution for infusion (10mg/ml) per administration based on upper weight limits of group (ml) | Maximum Daily Dose |
|---|-------------------------|---------------------------|--|------------------------------|
| ≤10 kg | 7.5 mg/kg | 0.75 mg/kg | 7.5ml | 30 mg/kg |
| <10 kg to ≤33kg | 15 mg/kg | 1.5 mg/kg | 49.5ml | 60 mg/kg Not exceeding 2g |
| > 33 kg to ≤50kg | 15 mg/kg | 1.5 mg/kg | 75ml | 60 mg/kg Not exceeding 3g |
| > 50 kg with additional risk factors for hepatotoxicity | 1g | 100ml | 100ml | 3g |
| > 50 kg and no additional risk factors for hepatotoxicity | 1g | 100ml | 100ml | 4g |

PHARMACOKINETICS

Adults

Absorption

Paracetamol pharmacokinetics is linear up to 2 g after single administration and after repeated administration during 24 hours.

The bioavailability of paracetamol following infusion of 500mg and 1 g of Paracetamol 10 mg/ml Solution for Infusion is similar to that observed following infusion of 1g and 2 g propacetamol (containing 500mg and 1 g paracetamol respectively). The maximal plasma concentration (C_{max}) of paracetamol observed at the end of 15-minutes intravenous infusion of 500mg and 1 g of Paracetamol 10 mg/ml Solution for Infusion is about 15µg/ml and 30 µg/ml respectively.

Distribution

The volume of distribution of paracetamol is approximately 1 L/kg. Paracetamol is not extensively bound to plasma proteins. Following infusion of 1 g paracetamol, significant concentrations of

significant anti-inflammatory activity.

MECHANISM OF ACTION

Despite its common use, the mechanism of action of paracetamol is not completely understood. Unlike NSAIDs such as aspirin, paracetamol does not appear to inhibit the function of any cyclooxygenase (COX) enzyme outside the central nervous system, and this appears to be the reason why it is not useful as an anti-inflammatory. It does appear to selectively inhibit COX activities in the brain, which may contribute to its ability to treat fever and pain. This activity does not appear to be direct inhibition by blocking an active site, but rather by reducing COX, which must be oxidized in order to function.

INDICATIONS

Paracetamol Infusion is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

paracetamol (about 1.5 µg/mL) were observed in the cerebrospinal fluid at and after the 20th minute following infusion.

Biotransformation

Paracetamol is metabolised mainly in the liver following two major hepatic pathways: glucuronic acid conjugation and sulfuric acid conjugation. The latter route is rapidly saturable at doses that exceed the therapeutic doses. A small fraction (less than 4%) is metabolised by cytochrome P450 to a reactive intermediate (N-acetyl benzoquinone imine) which, under normal conditions of use, is rapidly detoxified by reduced glutathione and eliminated in the urine after conjugation with cysteine and mercapturic acid. However, during massive overdosing, the quantity of this toxic metabolite is increased.

Elimination

The metabolites of paracetamol are mainly excreted in the urine. 90% of the dose administered is excreted within 24 hours, mainly as glucuronide (60-80%) and sulfate (20-30%) conjugates. Less than 5%

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Neonates, infants and children

The pharmacokinetic parameters of paracetamol observed in infants and children are similar to those observed in adults, except for the plasma half-life that is slightly shorter (1.5 to 2 h) than in adults. In neonates, the plasma half-life is longer than in infants i.e. around 3.5 hours. Neonates, infants and children up to 10 years excrete significantly less glucuronide and more sulfate conjugates than adults.

WARNINGS & PRECAUTIONS

It is recommended that a suitable analgesic oral treatment be used as soon as this route of administration is possible.

In order to avoid the risk of overdose, check that other medicines administered do not contain either paracetamol or propacetamol.

Doses higher than those recommended entail the risk of very serious liver damage. Clinical signs and symptoms of liver damage (including fulminant hepatitis, hepatic failure, cholestatic hepatitis, cytolytic hepatitis) are usually first seen after two days of drug administration with a peak seen usually after 4-6 days. Treatment with antidote should be given as soon as possible.

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor fetoneonatal toxicity. Epidemiological studies on

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲۰-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ اور گرمی سے محفوظ رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:

**PHARMASOL
PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.