For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

XTPARA SUSPENSION 250

1. Generic Name

Paracetamol Paediatric Oral Suspension I.P. 250mg

2. Qualitative and quantitative composition

Each 5ml contains:

Paracetamol I.P. …….250 mg

Colour: Carmoisine

The excipients used are Refined Sugar, Methyl Paraben, Propyl Paraben, Sodium Benzoate, Disodium EDTA, Citric Acid Monohydrate, Xanthan Gum, Sodium Saccharin, Sodium Chloride, Liquid Glucose, Sorbitol, Colour Carmoisine, Essence Strawberry and Neotame.

3. Dosage form and strength

Dosage form: Oral Suspension

Strength: Paracetamol 250 mg

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of mild to moderate pain and as an anti-pyretic. Used for the relief of pain and feverishness associated with teething, toothache, headache, colds and flu.

4.2 Posology and method of administration

Posology

The daily recommended Dose is 3-4 times a day or as directed by the physician.

For paediatric use only.

Method of administration

XTPARA SUSPENSION 250 is for Oral use only.

It is important to shake well before use.

4.3 Contraindications

Hypersensitivity to Paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

- Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.
- The label should contain the following statements:

- Contains paracetamol.
- Do not give this medicine with any other paracetamol-containing product.
- For oral use only.
- Never give more medicine than shown in the table.
- Do not overfill the spoon.
- Always use the spoon supplied with the pack.
- Do not give more than 4 doses in any 24 hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.
- As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
- Do not store above 25°C. Store in the original package.
- Keep all medicines out of the reach and sight of children.
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well (label).
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage (leaflet).

4.5 Drugs interactions

The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Drugs which induce hepatic microsomal enzymes such as alcohol. Concomitant barbiturates and tricyclic antidepressants may increase the hepatoxicity of Paracetamol particularly after overdose. Anti-convulsant or oral steroid contraceptives have the ability to reduce serum levels of Paracetamol by liver enzyme induction.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data does not contraindicate breast-feeding.

4.7 Effects on ability to drive and use machines

None Stated.

4.8 Undesirable effects

Very rare cases of serious skin reactions have been reported. Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to Paracetamol. With prolonged use or overdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

Overdose of paracetamol may be injurious to Liver.

Liver damage is possible in adults who have taken 10 g or more of Paracetamol. Ingestion of 5 g or more of Paracetamol may lead to liver damage if the patient has risk factors.

Risk Factors

If the patient:

(a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes.
or

(b) Regularly consumes ethanol in excess of recommended amounts.

or

(c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one 1 hour. Plasma Paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPIS or a liver unit.

5. Pharmacological properties

5.1 Mechanism of Action

Paracetamol produces analgesic and antipyretic as main effects and it has been also reported that paracetamol has a weak anti-inflammatory effect. Analgesic action: The central analgesic action of Paracetamol resembles that of aspirin. It produces analgesia by raising pain threshold. Antipyretic effect: The antipyretic effect of Paracetamol is attributed to its ability to inhibit COX in the brain where peroxide tone is low. Recent evidence suggests inhibition of COX-3 (believed to be splice variant product of the COX-1 gene) could represent a primary central mechanism by which Paracetamol decreases pain and possibly fever. Paracetamol is a peripherally acting analgesic with antipyretic activity.

5.2 Pharmacodynamic properties

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however to be on a selective basis.

5.3 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

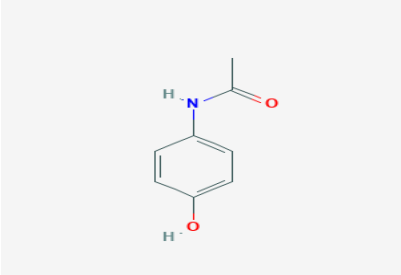
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC. Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

7. Description

Paracetamol is 4-hydroxyacetanilide having molecular formula of $C_8H_9NO_2$ and molecular weight is 151.2 and the chemical structure is:



Paracetamol is white crystals or white, crystalline powder which is freely soluble in ethanol (95%) and in acetone; sparingly soluble in water; very slightly soluble in dichloromethane and in ether.

Paracetamol Paediatric Oral Suspension is Pink colour Suspension with sweet taste and pleasant flavour filled in amber colour PET bottles. The excipients used are Refined Sugar, Methyl Paraben, Propyl Paraben, Sodium Benzoate, Disodium EDTA, Citric Acid Monohydrate, Xanthan Gum, Sodium Saccharin, Sodium Chloride, Liquid Glucose, Sorbitol, Colour Carmoisine, Essence Strawberry and Neotame.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

XTPARA SUSPENSION 250 is available in 60 ml pack.

8.4 Storage and handing instructions

Store below 30°C. Protect from direct sunlight.

Keep the medicines out of reach of children

9. Patient counselling information

XT PARA SUSPENSION 250

Paracetamol Paediatric Oral Suspension I.P. 250mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1 What XTPARA SUSPENSION 250 is and what it is used for

XTPARA SUSPENSION 250 contains paracetamol 250 mg/5 ml to relieve pain and reduce high temperatures. XTPARA SUSPENSION 250 can be used in children as directed by physician for the treatment of mild or moderate pain and feverishness associated with teething, toothache, headache, colds and flu.

9.2 What you need to know before you take XTPARA SUSPENSION 250

Do not give XTPARA SUSPENSION 250

If your child is taking any other paracetamol containing products, other flu, cold, cough or decongestant products, or alcohol

Do not give XTPARA SUSPENSION 250 to your child if he/she:

- is allergic (hypersensitive) to paracetamol, or any of the other ingredients of XTPARA SUSPENSION 250 (see Section 9.6).
- has kidney or liver problems

If you are not sure about any of the above, please consult your doctor

Take special care with XT PARA SUSPENSION 250

If your child does not get better, talk to your doctor.

Taking other medicines

Tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicine, even those obtained without a prescription, but especially medicines which:

- are to treat ‘flu’ or a cold, containing paracetamol and/or a decongestant
- thin the blood (e.g. warfarin)
- control nausea and vomiting (e.g. domperidone or metoclopramide)
- reduce levels of cholesterol and other fats in the blood (e.g. colestyramine)
- treat epilepsy (e.g. anti-convulsants)

- have been prescribed by your doctor to improve sleep (e.g. barbiturates), or for anxiety or depression (e.g. tricyclic antidepressants)

The effects of alcohol may be increased whilst taking XTPARA SUSPENSION 250.

Avoid alcohol when taking this medicine.

Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Driving and using machines

XTPARA SUSPENSION 250 is not expected to affect your ability to drive or operate machinery.

9.3 How to take

XTPARA SUSPENSION 250 should be taken 3-4 times a day or as directed by the physician. It is important to shake well before use.

If your child take more XTPARA SUSPENSION 250 than you should

Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take XTPARA SUSPENSION 250

If you miss a dose give it as soon as you remember and take any remaining doses for that day at evenly spaced times. Do not take a double dose to make up for the missed dose.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

9.4 Possible side effects

Like all medicines, XTPARA SUSPENSION 250 can cause side effects although not everybody gets them.

You or your child may notice the following:

- rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing, which may be signs of an allergic reaction. STOP giving XTPARA SUSPENSION 250 to your child immediately.
- blood disorders

Very rare cases of serious skin reactions have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store XTPARA SUSPENSION 250

Store below 30°C. Protect from direct sunlight.

9.6 Contents of the pack and other information

What **XTPARA SUSPENSION 250** contains

The active substances **XTPARA SUSPENSION 250** is Paracetamol.

The excipients used are Refined Sugar, Methyl Paraben, Propyl Paraben, Sodium Benzoate, Disodium EDTA, Citric Acid Monohydrate, Xanthan Gum, Sodium Saccharin, Sodium Chloride, Liquid Glucose, Sorbitol, Colour Carmoisine, Essence Strawberry and Neotame.

10. Details of manufacturer

Manufactured in India by:
Biogenetic Drugs Pvt Ltd.
Jharmazri, Baddi, Dist. Solan (H.P.)

11. Details of permission or licence number with date

Mfg Lic No. MNB-05/150 issued on 16.07.2015

12. Date of revision

Not Applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ XTPARA SUSPENSION 250mg/APR-20/01/PI