Bosch

For Medical Professional only

Bofalgan IM Injection

300mg/2mL Injection

(Paracetamol B.P.)

(Product Specs.: M.S.)

بوفالگن

۳۰۰ ملی گرام/ ۲ ملی لیٹر انجکشن

For Intramuscular Use Only

COMPOSITION:
Sterile, solution for injection
Each 2mL contains Paracetamol B.P. … 300mg

PHARMACOLOGICAL PROPERTIES:
Mechasim of Action:
Paracetamol inhibits the synthesis of prostaglandin in the central nervous system and peripherally blocks pain impulse generation; produces antipyresis from inhibition of hypothalamic heat-regulating center.

CLINICAL PARTICULARS:
Therapeutic Indications:
- High grade fever in patients who cannot tolerate oral medications.
- As an analgesic, paracetamol is indicated for postoperative patients where oral medication is not possible

DOSAGE:
Adults: 2-4 mL deep IM. Minimum interval of 4 hours recommended in-between doses, and 6 hours in those with hepatic and or renal impairment. Maximum of 1 gm up to 4 times daily.

Children: (<33 kg): 15 mg/kg paracetamol Injection IM / IV upto 4 times a day , approximately as follows:

· 7-12 years:	1.25	-	2 mL
· 3 - 6 years:	1	-	1.25 mL
· 1 - 2 years:	0.75	-	1 mL
· 6 - 12 months:	0.5	-	0.75 mL
· < 6 months:	0.25	-	0.5 mL

May be given 4-6 hrs via slow IV push or via deep IM injection while symptoms persist, but Maximum dose is 60 mg /kg per day or as directed by a physician.

CONTRAINDICATION
- Hypersensitivity to paracetamol or any component of the formulation.
- Severe hepatic impairment or severe active liver disease.

WARNINGS & PRECAUTIONS
- Ethanol use: Use with caution in patients with alcoholic liver disease; consuming 3 alcoholic drinks/day may increase the risk of liver damage.
- G6PD deficiency: Use with caution in patients with known G6PD deficiency; rare reports of hemolysis have been reported.
- Hepatic impairment: Use with caution in patients with hepatic impairment or active liver disease; use of the intravenous formulation is contraindicated in patients with severe hepatic impairment or severe active liver disease.
- Hypovolemia: Use the intravenous formulation with caution in patients with severe hypovolemia (eg, due to dehydration or blood loss).
- Renal impairment: Use with caution in patients with severe renal impairment (CrCl <30ml/min) consider dosing adjustments.
- Chronic malnutrition increases the risk of hepatic injury paracetamol should use with caution.
- It should not be administered to new born or premature infants.
- Caution in patients with chronic alcoholism (low reserves of glutathione stores) and dehydration.

ADVERSE EFFECTS
The following are some of the adverse effects that are known to be associated with paracetamol.

Adverse effects may include:
Very common (≥10%)
Gastrointestinal: Nausea (adults 34%; children ≥5%), vomiting (adults 15%; children ≥5%)
Common (1%-10%)
Cardiovascular: Edema (peripheral), hypervolemia, hypo/hypertension, tachycardia
Central nervous system: Headache (adults 10%; children ≥1%), insomnia (adults 7%; children ≥1%), agitation (children ≥5%), anxiety, fatigue

Dermatologic: Pruritus (children ≥5%), rash
Endocrine & metabolic: Hypoalbuminemia, hypokalemia, hypomagnesemia, hypophosphatemia
Gastrointestinal: Constipation (children ≥5%), abdominal pain, diarrhea
Hematologic: Anemia
Hepatic: Transaminases increased
Local: Infusion site pain
Neuromuscular & skeletal: Muscle spasms, pain in extremity
Ocular: Periorbital edema
Renal: Oliguria (children ≥1%)
Respiratory: Atelectasis (children ≥5%), breath sounds abnormal, dyspnea, hypoxia, pleural effusion, pulmonary edema, stridor, wheezing

PREGNANCY
Paracetamol injections is classified as pregnancy category C. Administer paracetamol injection for pregnant women only if clearly needed.

LACTATION
Use with caution because low concentrations of paracetamol are excreted into breast milk and can be detected in the urine of nursing infants. Adverse reactions have generally not been observed; however, a rash caused by paracetamol exposure is reported.

DRUG INTERACTIONS
Anticonvulsants: May increase the metabolism of Paracetamol. Or diminish the effect of paracetamol. Also may increase the risk of liver damage.

Conivaptan: May increase the serum concentration of CYP3A4 Substrates.

Dasatinib & Imatinib: Paracetamol may enhance the hepatotoxic effect of Dasatinib and Imatinib and may increase the serum concentration of Paracetamol.

Isoniazid: May enhance the adverse/toxic effect of Paracetamol.

Metyrapone: May increase the serum concentration of Paracetamol. More importantly, by inhibiting the conjugative metabolism of paracetamol, metyrapone may shift the metabolism towards the oxidative route that produces a hepatotoxic metabolite.

Peginterferon Alfa-2b: May decrease the serum concentration of CYP2D6 Substrates

Probenecid: May increase the serum concentration of Paracetamol. Probenecid may also limit the formation of at least one major non-toxic metabolite, possibly increasing the potential for formation of the toxic metabolite.

Sorafenib: Paracetamol may enhance the hepatotoxic effect of sorafenib and may increase the serum concentration of Paracetamol.

Tocilizumab: May decrease the serum concentration of CYP3A4 Substrates.

Vitamin K Antagonists (eg, warfarin): Paracetamol may enhance the anticoagulant effect of Vitamin K Antagonists. Most likely with daily paracetamol doses >1.3 g for >1 week.

Ethanol: Excessive intake of ethanol may increase the risk of paracetamol-induced hepatotoxicity. Avoid ethanol or limit to <3 drinks/day.

Laboratory Test: Urine glucose tests may produce false results while you are taking paracetamol.

OVERDOSE AND TREATMENT
Symptoms of overdosage may include nausea, vomiting, abdominal pain, diaphoresis, generalized weakness & lethargy. If an overdose of Paracetamol is suspected, blood should be withdrawn immediately for Paracetamol plasma assay, without regard to the presence or absence of symptomatology. The acute hepatotoxicity, nephrotoxicity of paracetamol can be overcome by the administration of sulfinydryl donors, e.g, N-acetyl cysteine which should be given as soon as possible after ingestion. Treatment after 12 hours is not effective. Paracetamol overdose should be treated with gastric lavage if the patient is seen within 24 hours of ingestion of the drug

DIRECTIONS
Protect from light, store at 25˚C. Do not freeze.
Not to be used if solution is not clear. Keep out of the reach of children.
For suspected adverse drug reaction for BOSCH products, report at ade@bosch-pharma.com

PACK: One pack of 5's IM injection of 2mL

WARNING: To be sold on prescription of a registered medical practitioner only.

ہدایات:

- 25°C درجہ حرارت پر روشنی سے محفوظ رکھیں۔ منجمد ہونے سے محفوظ رکھیں۔
- انجکشن میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

انتباہ : صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لئے۔

Manufactured by:
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ISO 9001:2015 Certified Company