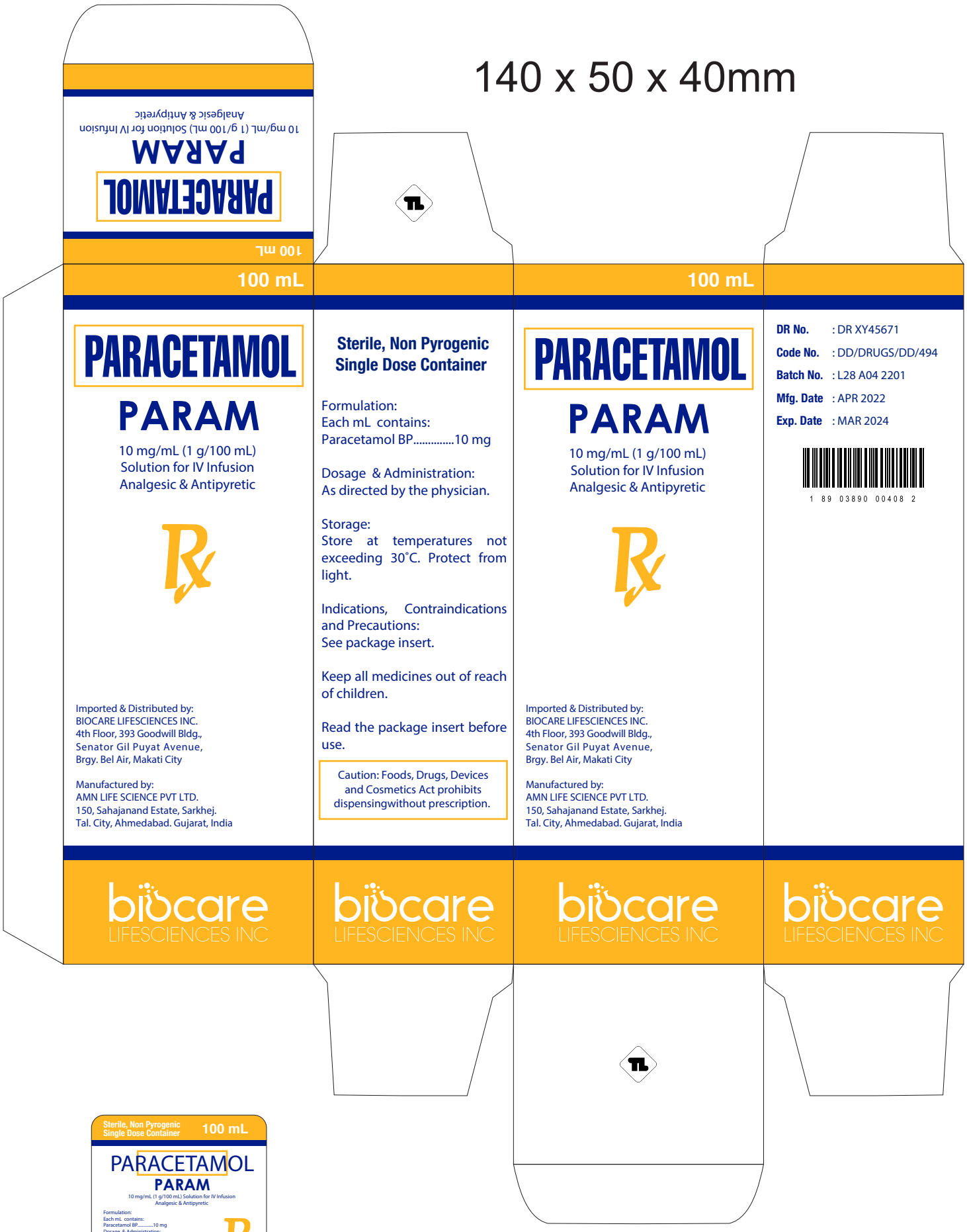
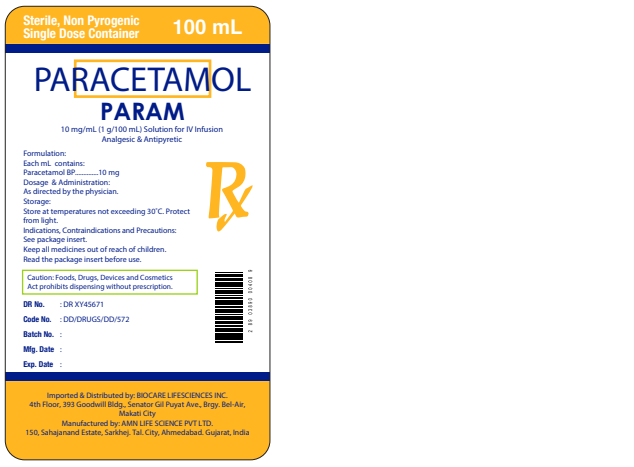
140 x 50 x 40mm





350GSM White back paper with varnish ITC board

		VIAL LABEL DIMENSIONS (MM)	(H) 60 x (L) 35		
GENERIC NAME	Paracetamol	PACK SIZE	100 mL	COLORS	
BRAND NAME	PARAM	DIMENSIONS (MM)	(H) 140 x (L) 50 x (W) 40		ReflexBlueC
DOSAGE FORM	Solution for IV Infusion	DOSAGE STR	10 mg/mL (1 g/100 mL)		1235 C

APPROVED BY:
SIGNATURE:
DATE:
REVISION NUMBER:

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

PARACETAMOL

PARAM

10 mg/mL (1 g/100 mL) Solution for IV Infusion
Analgesic & Antipyretic

Formulation :
Each mL contains:
Paracetamol BP.....10 mg

Indications
Paracetamol is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and for reduction of fever.

Dosage and Administration

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

Adolescents and adults weighing more than 50 kg:
Paracetamol 1 g per administration, up to four times a day or 650 mg every 4 hours to a maximum of 4 g per day period minimum dosing interval of 4 hours.

Children, adolescents and adults weighing less than 50 kg :
Paracetamol 15 mg/kg per administration, i.e. 1.5 mL solution per kg up to four times a day or 12.5 mg/kg every 4 hours to a maximum of 75 mg/kg per day. The minimum interval between each administration must be 4 hours.

"Severe renal insufficiency": it is recommended, when giving Paracetamol to patients with severe renal impairment (creatinine clearance 30 mL/min), to increase the minimum interval between each administration to 6 hours.

"In adults with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) and dehydration, the maximum daily dose must not exceed 3 g"

Contraindications
Paracetamol is contraindicated:
- in patients with hypersensitivity to Paracetamol or to proparacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients
- in cases of severe hepatic impairment or severe active liver disease.

Warnings and Precautions

Doses higher than those recommended entail the risk of very serious liver damage hepatic injury, including the rise of liver failure and death. 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.

Paracetamol should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended posology and duration must be strictly observed.

After oral administration, paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported. Consequently, paracetamol may be used in breast-feeding women.

Drug interaction:
Probenecid causes an almost 2-fold reduction in clearance of paracetamol by inhibiting its conjugation with glucuronic acid. A reduction in the paracetamol dose should be considered if it is to be used concomitantly with probenecid.
Salicylamide may prolong the elimination t½ of paracetamol.
Caution should be taken with the concomitant intake of enzyme-inducing substances.

Serious adverse effects:

- Hepatic injury
- Serious skin reactions
  - -Acute generalised exanthematous pustulosis (AGEP)
  - -Stevens-Johnson Syndrome (SJS)
  - -Toxic epidermal necrolysis (TEN)
- Allergy and hypersensitivity
  - -Swelling of the face, mouth and throat, respiratory distress, urticaria, rash, and pruritis.

Most common adverse effects:

Gastrointestinal disorder: Nausea, Vomiting
General disorders and administration site conditions: Pyrexia
Nervous system disorders: Headache
Psychiatric: Insomnia

Other adverse effects in Adults:

Blood Lymphatic system disorders: anemia
General disorders and administration site conditions: fatigue, infusion site pain, peripheral edema
Investigations: Aspartate aminotransferase increases breath sounds abnormal
Metabolism and Nutrition disorders: Hypokalemia
Musculoskeletal and connective tissue disorders: muscle spasms, tissues
Psychiatric disorders: anxiety
Respiratory, thoracic and mediastinal disorders: dyspnea
Vascular disorders: hypertension, hypotension

Other adverse effects in pediatrics:

Blood and lymphatics system disorders: anemia
Cardiac disorders: tachycardia
Gastrointestinal disorder: abdominal pain, diarrhea
General disorders and administration site conditions: injection site pain, peripheral edema, pyrexia
Investigations: hepatic enzyme increase
Metabolism and Nutrition disorders: hypoalbuminemia, hypokalemia, hypomagnesemia, hypophosphatemia, hypervolemia
Musculoskeletal and connective tissue disorders: muscle spasm, pain in extremity
Nervous system disorders: Headache
Psychiatric distress: Insomnia
Renal and urinary disorders: oliguria
Respiratory, thoracic and mediastinal disorders: pulmonary edema, hypoxia, pleural effusion, stridor, wheezing
Skin and subcutaneous tissue disorders: periorbital edema, rash
Vascular disorders: hypertension, hypotension.

Availability : Form Fill Seal LDPE bottle of 100 mL packed in a carton.

Storage : Store at temperatures not exceeding 30°C. Protect from light.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Caution : Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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