Summary of Products Characteristics(SmPC)

1. **Name of the medicinal Product**
   Paracetamol Injection 150 mg/ml

2. **Qualitative and Quantitative Composition**
   Each ml Contains.
   Paracetamol BP 150 mg
   Benzyl Alcohol 2 % v/v
   Water for Injection q.s.

Quantitative Composition:

Sr .No.	Name of the Materials	Specification	Label Claim	Quantity* /bottle	Active/ Inactive
1	Paracetamol	BP	150 mg	2250 mg	Active

Note: * Calculation based on potency.

3. **Pharmaceutical Form**
   IM/IV
   A clear colourless solution.

4. **Clinical Particulars**

1. Therapeutic Indications

Paracetamol 150 mg/ml solution for injection is indicated for the mild to moderate pain, pyrexia (pyrexia with discomfort in children).

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.

4.2 Posology and Method of Administration

Paracetamol 150 mg/ml solution for injection based in 10 mg/kg body weight, to be given via slowIV push or via deep IM injection, every 4-6 hours a day, or approximately as follows:

Age Group	***IV/IM dose every 4 to 6 hours***
Children	
<6 months	0.25-0.5 mL
6-12 months	0.5-0.75 mL
1-2 years	0.75-1 mL
3-6 years	1-1.25 mL
7-12 years	1.25-2 mL
Adults	2-4 mL

Method of administration: Paracetamol 150 mg/ml solution for injection may be given 4-6 hours via slow IV push or via deep IM injection while symptoms persist, but not to exceed 5 doses in each 24-hr period for not >5 days unless otherwise directed by a physician.

3. **Contraindications**

It is contraindicated in patients with known hypersensitivity to Paracetamol to any of the excipients of the formulation. In cases of severe hepatocellular insufficiency.

4. **Special Warnings and Special Precautions for Use**

Hepatic injury: Administration of Paracetamol in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. Do not exceed the maximum recommended daily dose of paracetamol.

Use caution when administering paracetamol in patients with hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance ≤ 30 mL/min).

Patients should take precaution if your baby is less than 4 weeks old, consult and take advice to your physician or pharmacist before giving them paracetamol 150 mg/ml solution for injection in particular if the baby is given other medicines that contain propylene glycol or alcohol.

Pregnancy: There are no studies of intravenous paracetamol in pregnant women; however, epidemiological data on oral Paracetamol use in pregnant women show no increased risk of major congenital malformations. Paracetamol injection should be given to a pregnant woman only ifclearly needed.

Lactation: Paracetamol is excreted in breast milk in small quantities. No undesirable effects on nursing infants have been reported. Paracetamol injection may be used in breast-feeding women.

5. **Interaction with other medicinal products and other forms of interaction**

Anticoagulants: Prolonged regular use of paracetamol possibly enhances anticoagulant effect of coumarins.

Antidiabetics: Absorption of paracetamol possibly reduced when given 1 to 4 hours after lixisenatide.

Antiepileptics: Metabolism of paracetamol possibly accelerated by carbamazepine, phenobarbital and phenytoin (also isolated reports of hepatotoxicity).

Cytotoxics: Paracetamol possibly inhibits metabolism of intravenous busulfan (manufacturer of intravenous busulfan advises caution within 72 hours of paracetamol); caution with paracetamol advised by manufacturer of imatinib.

Lipid-regulating Drugs: Absorption of Paracetamol reduced by colestyramine.

Metoclopramide: Rate of absorption of Paracetamol increased by metoclopramide.

6. **Pregnancy and Lactation**

Pregnancy: There are no studies of intravenous paracetamol in pregnant women; however, epidemiological data on oral Paracetamol use in pregnant women show no increased risk of majorcongenital malformations. Paracetamol injection should be given to a pregnant woman

only if clearly needed.

Lactation: Paracetamol is excreted in breast milk in small quantities. No undesirable effects on nursing infants have been reported. Paracetamol injection may be used in breast-feeding women.

7. **Effects on ability To Drive and use Machines**
Not relevant

8. **Undesirable effect**
Side-effects rare, malaise, skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis; blood disorders including thrombocytopenia, leucopenia, neutropenia reported; hypotension, flushing, and tachycardia reported on infusion.

9. **Overdose**
Symptoms: Acute overdose with Paracetamol may also lead to acute renal tubular necrosis. Symptoms generally appear within the first 24 hours and comprise of nausea, vomiting, anorexia, pallor and abdominal pain. 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, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis may occur.

Treatment: Treatment of paracetamol overdose may include the antidote N-acetyl cysteine (NAC) by the IV or oral route. In overdoses of oral paracetamol NAC is administered, if possible, before 10hours but may give some degree of protection from liver toxicity even after this time. Othersymptomatic and supportive treatment.

5. Pharmacological Properties

5.1. Pharmacodynamics Properties
Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanicalor chemical stimulation. Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2. Pharmacokinetic Properties
Absorption: Paracetamol pharmacokinetics is linear up to 2 g after single administration and after repeated administration during 24 hours.

Distribution: The volume of distribution of Paracetamol is approximately 1 L/kg.
Paracetamol is notextensively bound to plasma proteins.

Metabolism: Paracetamol Injection is metabolized mainly in the liver following two major hepatic pathways: glucuronic acid conjugation and sulphuric acid conjugation. The later 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.

Half-life: Plasma elimination half-life is approximately 2.7 hours.
Excretion: 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 sulphate (20-30%) conjugates. Less than 5% is eliminated unchanged.

5.3. Preclinical Safety Data

Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SmPC.
Studies on local tolerance of Paracetamol Solution for Infusion in rats and rabbits showed good tolerability. Absence of delayed contact hypersensitivity has been tested in guinea pigs.

6. Pharmaceutical Particulars

6.1. List of Excipients

Propylene Glycol

Benzyl Alcohol

Polyethylene Glycol- 400

Sodium Metabisulfite

Sodium Acetate Anhydrous

Glacial Acetic Acid

Sodium thiosulfate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

5. Nature and Contents of Container

Clear, colourless solution filled in 15ml amber glass vial such 10 vial packed in inner carton, such 5 inner carton packed in an outer carton along with pack insert.

6. Special precaution for disposal and other handling

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

7. Marketing Authorization Holder and Manufacturing Site

Name and Address of manufacturing site(s)
M/s Nitin Lifesciences Limited

Rampur Road, Paonta Sahib, District
Sirmour-173025 (HP), India

Marketing Authorization Holder
Chris Nelb pharmaceutical Nig . Ltd.
House 1,GH Close Festac Town, Loags , Nigeria

8. Marketing Authorization Number

B-4-9065

9. Date of first authorization/renewal of the authorization

03/10/2018

10.0 Date of Revision of the Text

13/02/2024