# Summary of Product Characteristics

# Provas® Injection

# Provas® Infusion

# Provas®
(Paracetamol)

## 1. NAME OF THE PRODUCT
**Provas®** (Paracetamol) Injection 300mg/2ml

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
**Provas® Injection 300mg/2ml**
Each 2ml contains:
Paracetamol BP.....300mg

## 3. PHARMACEUTICAL FORM
Solution for Injection

**Appearance:** Clear colorless to slightly colored solution, free from any visible particle.

## 4. CLINICAL PARTICULARS
### 4.1. THERAPEUTIC INDICATIONS:
**Provas®** Injection 300mg/2ml is indicated for the mild to moderate pain, pyrexia (pyrexia with discomfort in children).
Pyrexia of unknown origin, fever and pain, associated with common childhood disorders, tonsillitis, upper respiratory tract infection, postimmunization reactions, post operative fever, after tonsillectomy and other conditions, where patient is unable to take oral medications but where Paracetamol can be administered with advantage for prevention of febrile convulsion, headache, cold, sinusitis, muscle pain, arthritis and toothache.

### 4.2. POSOLOGY AND METHOD OF ADMINISTRATION:
**Posology:**
**Provas®** Injection 300mg/2ml based in 10mg/kg body weight, to be given via slow IV 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:**

**Provas®** Injection 300mg/2ml 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.

## 4.3. CONTRAINDICATIONS:

- It is contraindicated in patients with known hypersensitivity to Paracetamol to any of the excipients of the formulation.
- It is contraindicated in patients with anaemia, cardiac, pulmonary, and renal disease.
- It is contraindicated in cases of severe hepatocellular insufficiency.

## 4.4. SPECIAL WARNINGS AND 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 hypovolaemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance ≤30mL/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 300mg/2ml solution for injection in particular if the baby is given other medicines that contain propylene glycol or alcohol.

Do not take any Paracetamol containing medicines concurrently.

## 4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

**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.

## 4.6. FERTILITY, PREGNANCY AND LACTATION:

**Fertility:** No reproductive studies with the intravenous form of paracetamol have been performed in animals.

**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 if clearly needed.

**Breast-feeding:** 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.

## 4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not relevant.

## 4.8. UNDESIRABLE EFFECTS:

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

Toxicity may result from a single toxic dose of the drug or from chronic ingestion. The following adverse reactions have been reported: skin eruption, haematological toxicity.

## 4.9. 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 10 hours but may give some degree of protection from liver toxicity even after this time. Other symptomatic and supportive treatment.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1. PHARMACODYNAMIC EFFECTS:

**Pharmacotherapeutic group:** Analgesic and antipyretic.

**ATC Code:** N02BE01

**Mechanism of action:** 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 mechanical or chemical stimulation. Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating center 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. PHARMACOKINETICS:

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

**Distribution:** The volume of distribution of Paracetamol is approximately 1 L/kg. Paracetamol is not extensively 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 metabolized 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:

- Lidocaine HCl
- Propylene Glycol
- Sodium Citrate
- Sodium Meta Bisulphite

- Polyethylene Glycol
- Benzyl Alcohol
- Activated Charcoal
- Water for Injection

**6.2. INCOMPATIBILITIES:**

This medicinal product must not be mixed with other medicinal products except for dilution with 0.9% sodium chloride or 5% glucose solution.

**6.3. SHELF LIFE:**

See expiry on the pack.

**6.4. SPECIAL PRECAUTIONS FOR STORAGE:**

Avoid exposure to heat, light and freezing. Store between 15 to 30°C.
Improper storage may deteriorate the medicine.
Keep out of reach of children.

**6.5. NATURE AND CONTENTS OF CONTAINER:**

3ml clear amber glass ampoule USP Type-1, pack size is 5 x 2ml Ampoules.

**6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:**

Before administration, the product should be visually inspected for any particulate matter and discolouration. For single use only. Any unused solution should be discarded.

**6.7. DRUG PRODUCT SPECIFICATIONS:**

SAMI's Specs.

## 7. REGISTRATION / MARKETING AUTHORISATION HOLDER

Manufacturing & Release Site:
**SAMI Pharmaceuticals (Pvt.) Ltd.**
F-95, Off Hub River Road, S.I.T.E.,
Karachi-Pakistan
www.samipharma.com
Mfg Lic. No. 000072

Packing Site:
**SAMI Pharmaceuticals (Pvt.) Ltd.**
F-140/A, S.I.T.E., Karachi-Pakistan
Mfg Lic. No. 000938

## 8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)

022359

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

11th September, 1998

## 10. DATE OF REVISION OF THE TEXT

# پرورواس® انجکشن

## (پیراسیٹامول)

**ہدایات:**

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

# Provas®
## (Paracetamol)

**RISK OF MEDICATION ERRORS**

Take care to avoid dosing errors due to confusion between milligram (mg) and milliliter (ml), which could result in accidental overdose and death.

## 1. NAME OF THE PRODUCT

**Provas®** (Paracetamol) Infusion 1g/100ml

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Provas® Infusion 1g/100ml**

Each 100ml contains:

Paracetamol BP.....1g

## 3. PHARMACEUTICAL FORM

Solution for Infusion

**Appearance:** Clear colourless to slightly colored solution free from any visible particles.

## 4. CLINICAL PARTICULARS

### 4.1. THERAPEUTIC INDICATIONS:

Paracetamol is indicated for:

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

### 4.2. POSOLOGY AND METHOD OF ADMINISTRATION:

The 100ml bottle is restricted to adults, adolescents and children weighing more than 33kg.

**Posology:**

The dose to be administered and the bottle size to be used depend exclusively on the patient`s weight. The volume to be administered must not exceed the determined dose. If applicable the desired volume must be diluted in a suitable solution for infusion prior to administration or a syringe driver must be used. Dosing based on patient weight (please see the dosing table here below)

**100ml bottle:**

| Patient weight | Dose (per administration) | Volume per administration | Maximum volume of Paracetamol (10mg/ml) per administration based on upper weight limits of group (ml)*** | Maximum daily dose** |
|---|---|---|---|---|
| > 33kg to ≤ 50kg | 15mg/kg | 1.5ml/kg | 75ml | 60mg/kg not exceeding 3g |
| > 50kg with additional risk factors for hepatotoxicity | 1g | 100ml | 100ml | 3g |
| > 50kg and no additional risk factors for hepatotoxicity | 1g | 100ml | 100ml | 4g |

The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol containing products and should be adjusted accordingly taking such products into account.
*** Patients weighing less will require smaller volumes.
The minimum interval between each administration must be at least 4 hours. The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours. No more than 4 doses to be given in 24 hours.
**Severe renal insufficiency:** It is recommended, when giving paracetamol to patients with severe renal impairment (creatinine clearance ≤ 30ml/min), to reduce the dose and increase the minimum interval between each administration to 6 hours.
**Adults with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration:** The maximum daily dose must not exceed 3000mg.

**Method of administration:**
**Intravenous use:** The paracetamol solution is administered as a 15-minute intravenous infusion.

**Patients weighing ≤ 10kg:**

- The volume to be administered should be withdrawn from the ampoule and diluted in a sodium chloride 9mg/ml (0.9%) solution or glucose 50mg/ml (5%) solution or a combination of both solutions up to one tenth (one volume Paracetamol into nine volumes diluent) and administered over 15 minutes.
- A 5- or 10-ml syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume. However, this should never exceed 7.5ml per dose.
- The user should be referred to the product information for dosing guidelines.

Paracetamol can be diluted in a 9mg/ml (0.9%) sodium chloride solution or 50mg/ml (5%) glucose solution or a combination of both solutions up to one tenth (one volume Paracetamol into nine volumes diluent). In this case, use the diluted solution within the hour following its preparation (infusion time included). For instructions on dilution of the medicinal product before administration. For single use only. Any unused solution should be discarded. Before administration, the product should be visually inspected for any particulate matter and discoloration. Only to be used if the solution is clear, colorless or slightly pinkish-orangish (perception may vary) and the container and its closure are undamaged. As for all solutions for infusion presented in containers with air space inside, it should be remembered that close monitoring is needed notably at the end of the infusion, regardless of administration route. This monitoring at the end of the infusion applies particularly for central route infusions, in order to avoid air embolism.

## 4.3. CONTRAINDICATIONS:

- Hypersensitivity to paracetamol, propacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients.
- Cases of severe hepatocellular insufficiency.

## 4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Prolonged or frequent use is discouraged. It is recommended that suitable analgesic oral treatment will be used as soon as this route of administration is possible.

To avoid the risk of overdose, check that other medicines administered do not contain either paracetamol or propacetamol. The dose may require adjustment.

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.

Paracetamol should be used with caution in cases of:

- hepatocellular insufficiency

- severe renal insufficiency (creatinine clearance ≤ 30ml/min).
- chronic alcoholism
- chronic malnutrition (low reserves of hepatic glutathione)
- dehydration
- patients suffering from a genetically caused G-6-PD deficiency (favism), the occurrence of a haemolytic anaemia is possible due to the reduced allocation of glutathione following the administration of paracetamol.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

## 4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

- Probenecid causes an almost two-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 half-life of paracetamol.
- Caution should be taken with the concomitant intake of enzyme-inducing substances.
- Concomitant use of paracetamol (4000mg per day for at least 4 days) with oral anticoagulants may lead to slight variations of INR values. In this case, increased monitoring of INR values should be conducted during the period of concomitant use as well as for 1 week after paracetamol treatment has been discontinued.
- Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors.

## 4.6. FERTILITY, PREGNANCY AND LACTATION:

**Pregnancy:** A large amount of data on pregnant women indicates neither malformative, nor foeto/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:** 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.

## 4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not relevant.

## 4.8. UNDESIRABLE EFFECTS:

As with all paracetamol products, adverse drug reactions are rare (≥ 1/10 000 to <1/1 000) or very rare (<1/10 000). They are described below:

**Blood and Lymphatic system disorders:** ***Very rare:*** Thrombocytopenia, leucopenia, neutropenia.

**Immune system disorders:** ***Very rare:*** Hypersensitivity reaction.

**Cardiac disorders:** ***Not known:*** Tachycardia.

**Vascular disorders:** ***Rare:*** Hypotension. ***Not known:*** Flushing.

**Hepatobiliary disorders:** ***Rare:*** Increased levels of hepatic transaminases.

**Skin and subcutaneous tissue disorders:** ***Very rare:*** Serious skin reaction. ***Not known:*** Pruritus, erythema.

**General disorders and administration site conditions:** ***Rare:*** Malaise.

## 4.9. OVERDOSE

**Symptoms:** There is a risk of liver injury (including fulminant hepatitis, hepatic failure, cholestatic hepatitis, cytolytic hepatitis), particularly in elderly subjects, in young children, in patients with liver disease, in cases of chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers. Overdosing may be fatal in these cases. Symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor and abdominal pain. Immediate emergency measures are necessary in case of paracetamol overdose, even when no symptoms are present. Overdose, 7.5g or more of paracetamol in a single administration in adults or 140mg/kg of body weight in a single administration in children, causes hepatic cytolysis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with decreased prothrombin levels that may appear 12 to 48 hours after administration. Clinical symptoms of liver damage are usually evident initially after two days, and reach a maximum after 4 to 6 days.

**Treatment:**

***Immediate hospitalization:*** Before beginning treatment, take a blood sample for plasma paracetamol assay, as soon as possible after the overdose. The treatment includes administration of the antidote, N-acetylcysteine (NAC) by the intravenous or oral route, if possible before the 10th hour. NAC can, however, give some degree of protection even after 10 hours, but in these cases prolonged treatment is given.

***Symptomatic treatment:*** Hepatic tests must be carried out at the beginning of treatment and repeated every 24 hours. In most cases hepatic transaminases

restitution to normal in one to two weeks with full return of normal liver function. In very severe cases, however, liver transplantation may be necessary.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. PHARMACODYNAMIC EFFECTS:

**Pharmacotherapeutic group:** Analgesics; Other analgesics and antipyretics; Anilides.

**ATC Code:** N02BE01.

**Mechanism of action:** The precise mechanism of the analgesic and antipyretic properties of paracetamol has still to be established; it may involve central and peripheral actions. Paracetamol provides onset of pain relief within 5 to 10 minutes after the start of administration. The peak analgesic effect is obtained in 1 hour and the duration of this effect is usually 4 to 6 hours. Paracetamol reduces fever within 30 minutes after the start of administration with a duration of the antipyretic effect of at least 6 hours.

### 5.2. PHARMACOKINETICS:

**Absorption:** Paracetamol pharmacokinetics is linear up to 2g after single administration and after repeated administration during 24 hours. The bioavailability of paracetamol following infusion of 500mg and 1g of Paracetamol is similar to that observed following infusion of 1g and 2g propacetamol (containing 500mg and 1g paracetamol respectively). The maximal plasma concentration ($C_{max}$) of paracetamol observed at the end of 15-minutes intravenous infusion of 500mg and 1g of Paracetamol is about 15g/ml and 30µg/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 1g paracetamol, significant concentrations of paracetamol (about 1.5µg/ml) were observed in the cerebrospinal fluid at and after the $20^{th}$ minute following infusion.

**Metabolism:** Paracetamol is metabolised mainly in the liver following two major hepatic pathways: glucuronic acid conjugation and sulphuric 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 sulphate (20–30%) conjugates. Less than 5% is eliminated unchanged. Plasma half-life is 2.7 hours and total body clearance is 18 l/h.

**Newborn infants, 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 2h) than in adults. In newborn infants, the plasma half-life is longer than in infants i.e. around 3.5 hours. Newborn infants, infants and children up to 10 years excrete significantly less glucuronide and more sulphate conjugates than adults.

### 5.3. PRECLINICAL SAFETY DATA:

Non-clinical data reveal no special hazard for humans beyond the information included in other sections of the SmPC. Studies on local tolerance of paracetamol in rats and rabbits showed good tolerability. Absence of delayed contact hypersensitivity has been tested in guinea pigs. Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. LIST OF EXCIPIENTS:

- Mannitol
- Di-sodium hydrogen phosphate
- Sodium meta bisulphite
- Sodium hydroxide
- Water for Injection

### 6.2. INCOMPATIBILITIES:

Paracetamol must not be mixed other medicinal product except 0.9% sodium chloride for infusion or 5% glucose solution for infusion or a combination of both solutions up to one tenth.

### 6.3. SHELF LIFE:

**Unopened bottle:** See expiry on the pack.
**Opened bottle:** The infusion should commence immediately after connecting the bottle to the infusion set.
**After Dilution:** Chemical and physical in use stability (including infusion time) in the solutions mentioned above, has been demonstrated for 48 hours at 23°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storagetimes and conditions prior to use are the responsibility of the user.

### 6.4. SPECIAL PRECAUTIONS FOR STORAGE:

Do not store over 30°C, and protect from heat, light and freezing.
Improper storage may deteriorate the medicine.
Keep out of reach of children.

### 6.5. NATURE AND CONTENTS OF CONTAINER:

Clear 100ml glass bottle (USP Type-II) with bromobutyl stopper, sealed with tear-off seal, pack size is 1's.

### 6.6. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:

For single dose only. Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particles. Any unused solution should be discarded.

### 6.7. DRUG PRODUCT SPECIFICATION:

BP Specs.

## 7. REGISTRATION / MARKETING AUTHORISATION HOLDER

Manufacturing & Release Site:
**SAMI Pharmaceuticals (Pvt.) Ltd.**
F-95, Off Hub River Road, S.I.T.E.,
Karachi-Pakistan
www.samipharma.com
Mfg Lic. No. 000072

Packing Site:
**SAMI Pharmaceuticals (Pvt.) Ltd.**
F-140/A, S.I.T.E., Karachi-Pakistan
Mfg Lic. No. 000938

## 8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)

053223

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

29th November, 2008

## 10. DATE OF REVISION OF THE TEXT

# پروواس® انفیوژن
## (پیراسیٹامول)

**ہدایات:**

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،

گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں ورنہ دوا خراب ہو جائیگی۔

انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل پزیر

شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔