PROFESSIONAL INFORMATION

SCHEDULING STATUS: S3

1. NAME OF THE MEDICINE

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS

Solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL solution contains 10 mg paracetamol.

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: Each 50 mL solution contains 0,5 g of paracetamol.

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: Each 100 mL solution contains 1 g of paracetamol.

Excipient with known effect:

PARACETAMOL FRESENIUS contains mannitol (36,7 mg/mL).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

Clear, colourless to slightly yellowish solution free from visible particulate contamination.

pH: 5.0 - 7.0

Osmolality: 280 mOsm/L

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults and children (1 year and body mass 10 kg)

Short-term treatment of mild to moderate pain e.g., after dental procedures and minor orthopaedic surgery and the short-term treatment of fever when the oral route of administration is unsuitable.

4.2 Posology and method of administration

Posology

DO NOT EXCEED THE RECOMMENDED DOSE

The prescribed dose must be based on the patient's weight.

Unintentional overdose can lead to serious liver damage and death (see section 4.9). Healthcare providers are reminded that it is essential to follow both the weight-related dose recommendations and to consider individual patient risk factors for hepatotoxicity, including hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), and dehydration (see section 4.4).

Adults and adolescents weighing more than 50 kg:

PARACETAMOL FRESENIUS 1 g per administration (i.e., one 100 mL bottle/bag) up to 4 times a day.

The minimum interval between each administration must be 4 hours. The maximum daily dose must not exceed 4 g in 24 hours.

Adults and adolescents weighing less than 50 kg and children weighing more than 33 kg (approximately 11 years old):

PARACETAMOL FRESENIUS: 15 mg/kg per administration (i.e., 1,5 mL solution per kg) up to 4 times per day. The minimum interval between each administration must be 4 hours. The maximum daily dose must not exceed 60 mg/kg and must not exceed 3 g in 24 hours.

DOSING RECOMMENDATIONS ARE PRESENTED IN THE TABLE BELOW.

Patient weight (non-oedematous weight)	**Paracetamol dose (10 mg/mL) per administration**	**Minimum interval between each administration**	**Maximum daily dose***
> 50 kg	1 g (i.e. 100 mL bottle/bag) up to 4 times a day	4 hours	Must not exceed 4 g in 24 hours
> 33 kg and ≤ 50 kg	15 mg/kg (i.e. 1,5 mL solution per kg) up to 4 times a day	4 hours	≤ 60 mg/kg Must not exceed 3 g in 24 hours

* The maximum daily dose takes **into account all the medicines containing paracetamol.**

The dosage should be calculated on non-oedematous weight.

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

Paediatric use:

Restricted to children weighing more than 10 kg (approximately 1 year old).

DOSING RECOMMENDATIONS ARE PRESENTED IN THE TABLE BELOW.

Patient weight (non-oedematous weight)	**Paracetamol dose (10 mg/mL) per administration**	**Minimum interval between each administration**	**Maximum daily dose**
> 10 kg and ≤ 33 kg	15 mg/kg (i.e. 1,5 mL solution per kg) up to 4 times a day	4 hours	≤ 60 mg/kg Must not exceed 2 g in 24 hours

Severe renal insufficiency:

It is recommended to leave a minimum interval time of 6 hours between each administration in patients with severe renal impairment (creatinine clearance of ≤ 30 mL/min).

Hepatic impairment:

In patients with impaired hepatic function, the dose must be reduced or the dosing interval prolonged. The maximum daily dose should not exceed 60 mg/kg/day (not exceeding 2 g/day) in the following situations:

- adults weighing less than 50 kg
- chronic or compensated active hepatic disease, especially those with mild to moderate hepatocellular insufficiency
- Gilbert's syndrome (familial hyperbilirubinaemia)
- chronic alcoholism
- chronic malnutrition (low reserves of hepatic glutathione)
- dehydration.

Method of administration

Intravenous infusion.

For all patients, PARACETAMOL FRESENIUS is to be administered as a 15-minute intravenous infusion.

Close monitoring to avoid air embolism is needed, notably at the end of the infusion, especially if a central venous catheter is used for the infusion.

For instructions on dilution of the product before administration, see section 6.6.

4.3 Contraindications

PARACETAMOL FRESENIUS should not be used in:

- Patients that are hypersensitive to paracetamol, pro-paracetamol hydrochloride (pro-drug

of paracetamol), or any of the excipients of PARACETAMOL FRESENIUS (see section 6.1).

- Patients with severe hepatocellular insufficiency, or active liver disease including alcoholic hepatitis.
- Children weighing less than 10 kg (approximately 1 year old) (see sections 4.1, 4.2).

4.4 Special warnings and precautions for use

It is highly recommended to use the oral route of administration as soon as it is available.

To avoid the chance of overdose, check that any other medicines also used do not contain paracetamol. Higher doses than recommended can cause severe liver damage. The clinical signs of hepatic damage are usually seen first after 2 days with maximum damage seen after 4 – 6 days. Treatment with the antidote should be started as soon as possible as PARACETAMOL FRESENIUS overdose may be fatal (see section 4.9).

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS) / Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with PARACETAMOL FRESENIUS must immediately be discontinued and appropriate treatment instituted.

PARACETAMOL FRESENIUS contains paracetamol, which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that

the patient may be asymptomatic, the nearest doctor, hospital, or Poison Control Centre must be contacted immediately.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g., chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin.

If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Salicylates in prolonged treatment together with PARACETAMOL FRESENIUS significantly increase the risk of analgesic nephropathy, renal papillary necrosis, end-stage renal diseases, and cancer of the urinary bladder. Do not exceed the recommended individual dosages for salicylates and PARACETAMOL FRESENIUS (see section 4.5).

The anticoagulant effect could be increased when high doses of PARACETAMOL FRESENIUS are used together with anticoagulants, such as warfarin (see section 4.5).

The risk of PARACETAMOL FRESENIUS toxicity may be increased in patients receiving potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes (see section 4.5).

Patients suffering from alcoholism, hepatitis, recovering from liver damage or any form of liver disease or malnutrition should not be given high doses of PARACETAMOL FRESENIUS.

PARACETAMOL FRESENIUS should be used with caution in patients with mild to moderate liver impairment and it is contraindicated where there is active disease, particularly in alcoholic hepatitis.

PARACETAMOL FRESENIUS should be used with caution in patients with renal damage or disease, as prolonged excessive use of PARACETAMOL FRESENIUS can produce nephropathy. Paracetamol-induced renal function impairment may be sufficiently severe and could result in uraemia, especially with prolonged use of high doses. In patients with renal impairment with a creatinine clearance of 30 mL/minute or less, the elimination of PARACETAMOL FRESENIUS is delayed, therefore a 6 hourly dose interval is recommended (see section 4.2).

PARACETAMOL FRESENIUS should be used with caution in the following cases:

- Patients with renal damage or disease.
- Patients with severe renal insufficiency (creatinine clearance ≤ 30 mL/min) (see section 4.2).
- Hepatocellular insufficiency, including Gilbert's syndrome (familial hyperbilirubinaemia) (see sections 4.2, 4.3).
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency which may lead to haemolytic anaemia.
- Chronic alcoholism, excessive alcohol intake (three or more alcoholic drinks every day).
- Anorexia, bulimia or cachexia, chronic malnutrition (low reserves of hepatic glutathione).
- Dehydration, hypovolaemia.

4.5 Interaction with other medicines and other forms of interaction

Effect of other medicines on PARACETAMOL FRESENIUS:

- Phenytoin administered concomitantly with PARACETAMOL FRESENIUS may result in decreased paracetamol efficacy and an increased risk of hepatotoxicity. Patients receiving phenytoin should avoid large and/or chronic doses of PARACETAMOL FRESENIUS. Patients should be monitored for evidence of hepatotoxicity.
- Probenecid could increase the plasma concentrations of PARACETAMOL FRESENIUS by almost a 2-fold reduction in the clearance of paracetamol, by inhibiting its conjugation with glucuronic acid. A reduction of the PARACETAMOL FRESENIUS dose should be considered when administered concomitantly with probenecid.
- The absorption of PARACETAMOL FRESENIUS may be accelerated when used together with metoclopramide.
- Salicylamide may prolong the elimination half-life of PARACETAMOL FRESENIUS.
- Salicylates in prolonged treatment together with PARACETAMOL FRESENIUS significantly increase the risk of analgesic nephropathy, renal papillary necrosis, end-stage renal diseases, and cancer of the urinary bladder. The recommended individual doses for PARACETAMOL FRESENIUS and the salicylates should not be exceeded.
- Medicines that induce liver microsomal enzymes such as barbiturates or primidone could decrease the therapeutic effect of PARACETAMOL FRESENIUS.
- Concomitant intake of PARACETAMOL FRESENIUS with hepatic enzyme-inducing substances should be cautioned as these substances increase the risk of paracetamol induced liver injury. These substances include, but are not limited to, barbiturates, rifampicin, isoniazid, phenytoin, carbamazepine, anticoagulants, zidovudine, amoxicillin, clavulanic acid, chronic use of alcohol or hepatotoxic medicines (see section 4.9).
- Flucloxacillin: Caution is advised when PARACETAMOL FRESENIUS is administered concomitantly with flucloxacillin due to the increased risk of high anion gap metabolic acidosis (HAGMA) caused by pyroglutamic acidosis, particularly in patients with a risk factors (see section 4.4).

Effect of PARACETAMOL FRESENIUS on other medicines:

- PARACETAMOL FRESENIUS may increase the chance of unwanted effects when administered with other medicines.
- Anticoagulants: Concomitant use of PARACETAMOL FRESENIUS (4 g per day for at least 4 days) with coumarins, including warfarin, and/or indandione derivatives, may lead to increase in anticoagulant effects and variations in 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 FRESENIUS treatment has been discontinued.

4.6 Fertility, pregnancy and lactation

Pregnancy

Clinical experience of intravenous administration of PARACETAMOL FRESENIUS in pregnant women is limited. However, epidemiological data from the use of oral therapeutic doses of paracetamol indicate no undesirable effects on the pregnancy or on the health of the foetus/newborn infant. A large amount of data on pregnant women indicates neither malformative nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results.

Prospective data on pregnancies exposed to overdose did not show an increase in malformation risk.

Reproductive studies with the intravenous form of paracetamol have not been performed in animals. However, studies with the oral route did not show any teratogenic or fetotoxic effects. Nevertheless, PARACETAMOL FRESENIUS should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended dosage and duration must be strictly observed.

Breastfeeding

After oral administration paracetamol is excreted into breastmilk in small quantities. Rash in nursing infants has been reported. No undesirable effects on breastfed infants have been

reported with frequent use. However, caution should be used when administering PARACETAMOL FRESENIUS to woman who are breastfeeding.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

PARACETAMOL FRESENIUS has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions

System organ class	Less frequent	Frequency unknown
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis Leukopenia Pancytopenia Neutropenia Anaemia	
Immune system disorders	Hypersensitivity Anaphylactic shock Angioedema	
Metabolism and nutrition disorders		High anion gap metabolic acidosis*
Endocrine disorders	Pancreatitis	
Cardiac disorders		Tachycardia
Vascular disorders	Hypotension	
Gastrointestinal disorders		Nausea

		Vomiting
Hepatobiliary disorders	Increased levels of hepatic transaminases Hepatitis	Fulminant hepatitis Hepatic necrosis Hepatic failure
Skin and subcutaneous tissue disorders	Dermatitis Skin rash Urticaria Erythema Pruritus Acute generalised exanthematous pustulosis Toxic epidermal necrolysis Stevens-Johnson syndrome	Flushing Drug-induced hypersensitivity syndrome (DIHS) Fixed drug eruptions (FDE)
Renal and urinary disorders	Renal colic Renal failure Sterile pyuria	
General disorders and administration site conditions	Malaise	Administration site reactions

*High anion gap metabolic acidosis: Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Post-marketing experience

Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

4.9 Overdose

See sections 4.4 and 4.8.

Overdosage with PARACETAMOL FRESENIUS can result in severe liver damage and sometimes acute renal tubular necrosis. **Prompt treatment is essential**. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Susceptibility to PARACETAMOL FRESENIUS toxicity is increased in patients who have taken repeated high doses (greater than 5 – 10 g/day) of paracetamol for several days.

There is a risk of poisoning, particularly in elderly subjects, in young children, in patients with liver disease, in cases of chronic alcoholism, in patients with chronic malnutrition, AIDS and with the use of medicines that induce liver microsomal oxidation such as barbiturates,

isoniazid, rifampicin, phenytoin and carbamazepine (see section 4.5). Overdosing may be fatal in these cases.

Symptoms of overdose:

Symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor and abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours or later after administration, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time/increased INR. Liver damage may lead to encephalopathy, coma and death. Overdose with a single administration of 7,5 g or more of paracetamol in adults or 140 mg/kg of body weight in children, causes cytolytic hepatitis likely to induce complete and irreversible hepatic necrosis, resulting in acute or fulminant hepatic failure, 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. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac dysrhythmias have been reported.

Treatment of PARACETAMOL FRESENIUS 10 mg/mL overdose:

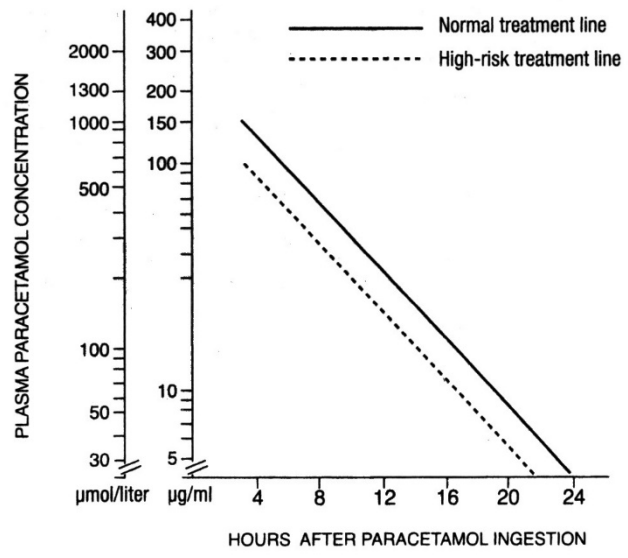
- Immediate hospitalisation.
- Before beginning treatment, take a tube of blood for plasma paracetamol assay, as soon

as possible after the overdose.

- N-acetylcysteine (NAC) should be administered in all cases of suspected overdose as soon as possible, preferably within eight hours of overdosage; although treatment up to 36 hours after administration may still be of benefit especially if more than 150 mg/kg of paracetamol was administered. An initial dose of 150 mg/kg N-acetylcysteine in 200 mL dextrose 5 % *m/v* injection given intravenously over 15 minutes, followed by an infusion of 50 mg/kg in 500 mL dextrose 5 % *m/v* injection over the next four hours and then 100 mg/kg in 1 000 mL dextrose 5 % *m/v* injection over the next sixteen hours. Sodium chloride 0,9 % *m/v* may be used where dextrose 5 % *m/v* is unsuitable.

  The volume of intravenous fluid should be modified for children.

  Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.



Source: Goodman & Gilman's The Pharmacological Basis of Therapeutics, 11th ed

Those, whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". *(Refer to the paracetamol nomogram above)*. Prothrombin index correlates best with survival.

Monitor all patients with significant overdose for 96 hours.

- Symptomatic treatment.
- Hepatic tests must be carried out at the beginning of treatment and repeated every 24 hours. In most cases hepatic transaminases return to normal in one to two weeks with full restitution of the liver function. In very severe cases, however, liver transplantation may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.7 Antipyretics or antipyretic and anti-inflammatory analgesics

Pharmacotherapeutic group: Other analgesics and antipyretics.

ATC code: N02BE01

Mechanism of action:

Paracetamol has analgesic and antipyretic activities.

Paracetamol has centrally and peripherally acting analgesic and antipyretic properties. The mechanism of action has not been established.

5.2 Pharmacokinetic properties

Absorption:

In adults, paracetamol pharmacokinetics is linear up to 2 g after single administration and after repeated administration during 24 hours. The maximal plasma concentration (C_{max}) of paracetamol observed at the end of 15 minutes intravenous infusion of 1 g of paracetamol in adults is approximately 30 µg/mL.

Distribution:

The volume of paracetamol distribution is about 1 L/kg. Paracetamol does not bind extensively to plasma proteins. After the infusion of 1 g of paracetamol in adults, significant concentrations

of paracetamol were observed in the cerebrospinal fluid after about 20 minutes (about 1,5 µg/mL).

Metabolism:

Paracetamol is metabolised mostly by the liver through two major pathways: glucuronic acid conjugation and sulphuric acid conjugation. The sulphuric acid conjugation pathway is highly saturable at doses that exceed the recommended therapeutic doses. A small amount (less than 4 %) is metabolised by cytochrome P450 to a reaction intermediate (N-acetyl benzoquinoneimine) which, under normal conditions of use is quickly detoxified by reduced glutathione and eliminated in the urine after conjugation with cysteine and mercapturic acid. However, during massive poisoning, the quantity of this toxic metabolite is highly increased.

Elimination:

Paracetamol metabolites are mainly excreted in the urine, of which 90 % of the dose is excreted within 24 hours. Less than 5 % is excreted unchanged, the rest as glucuronide (± 70 %) and sulphate (± 25 %) conjugates. Total body clearance of paracetamol is 18 L/hour and plasma elimination half-life is about 2,7 hours.

Children:

The pharmacokinetic parameters of paracetamol observed in children are similar to those observed in adults, except for the plasma half-life that is slightly shorter (1,5 to 2 h) than in adults.

Total excretion of paracetamol and its metabolites is the same at all ages.

Special populations:

The only pharmacokinetic parameters of paracetamol different in children than in adults are the plasma half-life which is slightly shorter (± 2 hours). The total excretion rate of paracetamol stays the same at all ages.

Patients with renal insufficiency:

The elimination half-life of paracetamol is significantly impaired (± 2 – 5,3 hours) in patients with severe renal impairment (creatinine clearance ≤ 30 mL/min). The elimination of the conjugates, glucuronide and sulphate is up to three times slower than in normal patients.

It is therefore recommended that the dose interval between administrations be at least 6 hours in patients with severe renal impairment (creatinine clearance ≤ 30 mL/min) (see section 4.2).

Hepatic impairment:

Paracetamol should be used with caution in patients with mild to moderate liver impairment and is contraindicated when there is active disease, particularly alcoholic hepatitis because of CYP 2E1 induction, which leads to increased formation of the hepatotoxic metabolite of paracetamol (see section 4.3).

Elderly patients:

No dose adjustment is required for elderly patients as the pharmacokinetics and metabolism of paracetamol do not change in these patients.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cysteine, mannitol and water for injection.

Contains mannitol (36,7 mg/mL).

6.2 Incompatibilities

PARACETAMOL FRESENIUS should not be mixed with other medicines.

PARACETAMOL FRESENIUS should only be diluted with those infusion solutions which are recommended (see section 6.6).

6.3 Shelf life

Unopened: 24 months.

After opening: Once opened, the contents should be used immediately. Discard any unused portion.

Diluted solutions: After dilution in 0,9 % sodium chloride: do not store for more than 1 hour (infusion time included).

6.4 Special precautions for storage

Glass bottles: Store at or below 30 °C.

Free*flex*® bags: Store at or below 25 °C.

Do not refrigerate or freeze.

For storage of the diluted solutions, see section 6.3.

6.5 Nature and contents of container

Packed into 50 mL or 100 mL clear, colourless glass bottles with a red rubber stopper and an aluminium cap with either a tear-off tab of aluminium or a plastic lid or into 50 mL and 100 mL **Free*flex*®** bags (polyolefin) closed with stoppers and plastic tamper-evident covers.

10, 12 or 20 glass bottles of 50 mL or 100 mL are packed with a leaflet into a cardboard box.

10, 20, 50 or 60 **Free*flex*®** bags of 50 mL or 100 mL are packed with a leaflet into a cardboard box.

Not all pack sizes or container closure systems may be marketed.

6.6 Special precautions for disposal and other handling

Before administration, the product should be visually inspected for any particulate matter and discolouration. It is intended for single use only. Once opened, the bottle/bag should be used immediately.

Any unused solution should be discarded.

PARACETAMOL FRESENIUS may be diluted up to one-tenth (one volume PARACETAMOL FRESENIUS into nine volumes diluent) in 0,9 % sodium chloride solution or a 5 % glucose solution. The volume of the diluted solutions should take into account the total volume of fluid to be administered to the patient as well as the medical condition of the patient.

When PARACETAMOL FRESENIUS (50 mL bottle/bag) is diluted as recommended, the total volume of diluted solution to be administered must be infused within one hour of its preparation (infusion time included).

7. HOLDER OF CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street, Halfway House extension 7

Midrand, Gauteng, 1685

South Africa

Telephone number: +27 (0)11 545 0000

8. REGISTRATION NUMBERS

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: 45/2.7/0531

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: 45/2.7/1188

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 December 2013

10. DATE OF REVISION OF THE TEXT

21 January 2026