SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT:

Paravin® 1000mg/100ml solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL vial contains:
Paracetamol.....1000 mg
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for infusion.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).
The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.
It is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

4.2 Posology and Method of Administration

Intravenous use.
The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg. close monitoring is needed before the end of the infusion.

Dosage

Dosing based on patient weight (please see the dosing table here below)

Patient weight	**Dose per administration**	**Volume per administration**	**Maximum volume of Paravin (10 mg/mL) per administration based on upper weight limits of group (mL)*** **	**Maximum Daily Dose ** **
≤10 kg*	7.5 mg/kg	0.75 mL/kg	7.5mL	30 mg/kg
> 10 kg to ≤33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g

> 50 kg and no additional risk factors for hepatotoxicity	1g	100mL	100mL	4g

*** Pre-term newborn infants:** No safety and efficacy data are available for pre-term newborn.
**** Maximum daily dose:** 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.

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.

The paracetamol solution is administered as 15 minutes intravenous infusion.
Patients weighing ≤ 10 kg:
• The glass vial of **Paravin** should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
• The volume to be administered should be withdrawn from the vial and diluted in a 0.9% sodium chloride solution or in 5% glucose solution up to one tenth (one volume **Paravin** 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.
For the 100ml vial, a 0.8 mm needle (21 gauge) and vertically perforate the stopper at the spot specifically indicated.
It can also be diluted in 0.9% sodium chloride or 5% glucose up to one tenth dilution (one volume **Paravin** into nine volumes diluent).
The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter or precipitate are found.
If you have the impression that the effect of **Paravin** 10 mg/ml, solution for infusion is too strong or too weak, talk to your doctor.
If you use more Paravin 10mg/ml solution for infusion than you should, contact your doctor or pharmacist immediately.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4.3 Contraindications

if you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of Paravin.
if you are allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol)
if you suffer from a severe liver disease.

4.4 Special Warnings and Precautions for Use

Use a suitable analgesic oral treatment as soon as this administration route is possible.
if you suffer from a liver or kidney disease, or from alcohol abuse,
if you are taking other medicines containing paracetamol,
In cases of nutrition problems (malnutrition) or dehydration.
Inform your doctor before treatment if any of the above-mentioned conditions applies to you.

Important information about some of the ingredients of Paravin 10 mg/ml, solution for infusion

275.1 mg of Na has been used in the formula of Paravin as tonicity agent,
To be taken into consideration by patients on a controlled sodium diet.
Before administration, the product should be inspected visually. Do not use **Paravin** if you notice any particulate matter and discoloration.
For single use only, the product should be used immediately after opening, any unused solution should be discarded.

4.5 Interactions with other Medicaments and other forms of Interaction:

This medicine contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see following section). Inform your doctor if you are taking other medicines containing paracetamol or propacetamol.
A reduction of the paracetamol dose should be considered for concomitant treatment with Probenecid.
Inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.
Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

4.6 Pregnancy and Lactation:

Pregnancy

Inform your doctor if you are pregnant. **Paravin** may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Paravin may be used during breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

4.7 Effects on Ability to Drive and Use Machines

NA

4.8 Undesirable Effects

Like all medicines, **Paravin** 10 mg/ml, solution for infusion can cause side effects, although not everybody gets them.
In rare cases (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons), the following may occur: a malaise, a drop in blood pressure or changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.
In very rare cases (less than 1 out of 10,000 persons, including isolated reports), a serious skin rash or allergic reaction may occur. **Stop the treatment** immediately and inform your doctor.
In isolated cases, other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor.
Cases of redness of the skin, flushing, itching and abnormally rapid beating of the heart have been reported.
Cases of pain and burning sensation at injection site have been reported.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain and a risk of liver injury.

5 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: OTHER ANALGESICS AND ANTIPYRETICS, ATC code: N02BE01 The precise mechanism of the analgesic and antipyretic properties of paracetamol has yet to be established; it may involve central and peripheral actions.
PARAVIN 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.
PARAVIN reduces fever within 30 minutes after the start of administration with

a duration of the antipyretic effect of at least 6 hours.

5.2 Pharmacokinetic Properties

Adults:

Absorption:

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

The bioavailability of paracetamol following infusion of 500 mg and 1 g of PARACETAMOL is similar to that observed following infusion of 1 g and 2 g propacetamol (corresponding to 500 mg and 1 g paracetamol respectively). The maximal plasma concentration (Cmax) of paracetamol observed at the end of 15-minutes intravenous infusion of 500 mg and 1 g of PARACETAMOL is about 15 µg/mL and 30 µg/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 1 g paracetamol, significant concentrations of paracetamol (about 1.5 µg/mL) were observed in the Cerebro Spinal Fluid as and from the 20th 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 in 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.

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

Table. Age related pharmacokinetic values (standardized clearance, * CLstd/Foral (l.h-1 70 kg-1), are presented below.

Age	Weight (kg)	CLstd/Foral (l.h-1 70 kg-1)
40 weeks PCA	3.3	5.9

3 months PNA	6	8.8
6 months PNA	7.5	11.1
1 year PNA	10	13.6
2 years PNA	12	15.6
5 years PNA	20	16.3
8 years PNA	25	16.3

*CLstd is the population estimate

for CL Special populations:

Renal insufficiency

In cases of severe renal impairment (creatinine clearance 10-30 mL/min), the elimination of paracetamol is slightly delayed, the elimination half-life ranging from 2 to 5.3 hours. For the glucuronide and sulphate conjugates, the elimination rate is 3 times slower in subjects with severe renal impairment than in healthy subjects. Therefore, 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 (see section 4.2. Posology and method of administration).

Elderly subjects

The pharmacokinetics and the metabolism of paracetamol are not modified in elderly subjects. No dose adjustment is required in this population.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium
metabisulfite
Histidine
Hydrochloric acid
Water for injection.

6.2 Incompatibilities

NA

6.3 Shelf Life

Two years

6.4 Special Precautions for Storage

Do not store above 30°C, do not refrigerate or freeze.

6.5 Nature and Contents of Container

Class vial 100ml Type (II) and Rubber stopper 32 mm

6.6 Instruction for Use/Handling

NA

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING ADRESS

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06-4162905

8.0 MARKETING AUTHORIZATION NUMBER:

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9.0 DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION

2025 September 19

10.0 DATE OF REVISION OF TEXT

2025 September 19