PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

INTRAMOL solution for intravenous infusion containing 1 000 mg **paracetamol** per 100 ml.

Read this entire leaflet carefully before INTRAMOL is administered to you.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or pharmacist.
- INTRAMOL has been prescribed for you personally and you should not share medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT INTRAMOL CONTAINS

Each 100 ml vial contains 1 000 mg paracetamol as active ingredient (each 1 ml of infusion contains 10 mg of paracetamol).

Inactive ingredients: Anhydrous disodium hydrogen phosphate, mannitol; water for injection. Contains mannitol.

2. WHAT INTRAMOL IS USED FOR

INTRAMOL is a solution for intravenous infusion and used for the short-term treatment of mild to moderate pain and/or fever, when the oral route is unsuitable.

3. BEFORE INTRAMOL IS GIVEN TO YOU

You should not be given INTRAMOL if

- you are allergic or hypersensitive to paracetamol or any other ingredient used in the INTRAMOL formulation

- you have severe liver problems, including alcoholic hepatitis
- if you weigh less than 33 kg (approximately 11 years old)

Take special care before INTRAMOL is given to you if

- you have severe kidney problems
- you are taking other medicines containing paracetamol as large doses of paracetamol may cause liver disease
- you are using alcohol daily (3 or more alcoholic drinks every day)
- you are dehydrated e.g. after vomiting and/or diarrhoea
- you are suffering from eating disorders such as anorexia, bulimia or cachexia
- you are in shock (which results in a decreased blood volume)
- you suffer from glucose-6-phosphate dehydrogenase deficiency. It is a hereditary disease characterised by abnormally low levels of glucose-6-phosphate dehydrogenase, a metabolic enzyme.

If any of these apply to you, **tell your doctor.**

Serious skin reactions like toxic epidermal necrolysis (TEN), Steven-Johnson syndrome, acute generalised exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/drug-induced hypersensitivity syndrome, and fixed drug eruptions have been observed in patients receiving paracetamol-containing medicines such as INTRAMOL. Stop using INTRAMOL and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 5.

Dosages in excess of those recommended may cause severe liver damage.

Signs and symptoms of overdose are usually seen first after two days with a maximum usually after 4 to 6 days. Treatment of an overdose should be started as soon as possible.

Your doctor will switch to suitable pain treatment taken by mouth as soon as you are able swallow.

INTRAMOL contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison centre must be contacted immediately.

Special caution is advised in patients with kidney function impairment. Prolonged administration of INTRAMOL can cause damage to your kidneys.

You are at an increased risk of developing a paracetamol overdose if you are currently on medicines that are hazardous to your liver or that affect your liver enzymes (see "Receiving INTRAMOL with other medicines").

If you are suffering from alcoholism, any liver disease, or condition that results from eating a diet in which certain nutrients are lacking (nutritional problems), you are at risk of liver damage. INTRAMOL should not be administered in excessive quantities to you.

Using INTRAMOL with food and drink

INTRAMOL can be used with or without food.

Pregnancy and breastfeeding

No unwanted reactions have been reported in pregnant women or in the unborn foetus with oral preparations of paracetamol. Clinical experience with the intravenous preparations of paracetamol such as in INTRAMOL is limited. If you are pregnant or breastfeeding your baby while INTRAMOL is administered to you, please inform your doctor, pharmacist or other health care professional.

Driving and using machines

You should consult your doctor about driving or operating machinery after being discharged from hospital. INTRAMOL should have no influence on your ability to drive and use machines.

Receiving INTRAMOL with other medicines

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of INTRAMOL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

INTRAMOL may interact with the following medicines:

- if you take salicylates like aspirin together with INTRAMOL it increases the risk of kidney diseases. Do not exceed the recommended individual dosages for salicylates and paracetamol.
- non-steroidal anti-inflammatory medicines (ibuprofen, naproxen, etc.).
- probenecid (medicine used for gout) may influence the activity duration of paracetamol.
- barbiturates (medicine used to calm/sedate) and/or primidone and carbamazepine (medicines used for epilepsy) increase the risk of liver toxicity.
- isoniazid and rifampicin (used in the treatment of tuberculosis) increase the risk of liver toxicity.
- zidovudine (used in the treatment of HIV/AIDS) increases the risk of liver toxicity.
- warfarin (used for thinning blood) used together with INTRAMOL may increase the risk of bleeding.

4. HOW TO RECEIVE INTRAMOL

INTRAMOL is usually given by a doctor or nurse who will inject INTRAMOL into a vein.

DO NOT EXCEED THE RECOMMENDED DAILY DOSE.

For patients with kidney problems the minimum dosing interval between administrations should be at least every 6 hours.

A lower dosage of INTRAMOL is given to low weight adults and adolescents weighing less than 50 kg and children more than 33 kg.

If more INTRAMOL is administered to you than stated or if a dose is missed

As INTRAMOL is administered by your doctor of nurse, this is highly unlikely.

If you are experiencing nausea, vomiting, loss of appetite, stomach pain, or you do feel that the dosage given to you is too strong, please talk to your doctor.

5. POSSIBLE SIDE EFFECTS

INTRAMOL can cause side effects.

Not all side effects reported for INTRAMOL are included in this leaflet. Should your general health worsen while using INTRAMOL, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor <u>immediately</u> if any of the following side effects occur

- allergic reactions with symptoms such as swelling of the face, eyelids, throat and lips and/or itchiness of the skin
- liver problems presented with the following symptoms: pain in the stomach area, nausea, vomiting, tiredness and sweating
- severe pain in the kidneys (lower back area)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INTRAMOL. You may need urgent medical attention. Other side effects may occur, please tell your doctor as soon as possible.

The following side effects have been reported less frequently

- skin irritations
- signs of recurrent infections such as fever or sore throat
- low blood pressure or e.g. feeling dizzy when moving from sitting to standing position
- bleeding from the nose or gums which may indicate low levels of blood platelets
- rapid heart beating
- general unwell feeling
- pain or burning sensation at the injection site

- inflammation of the liver characterised by poor appetite, yellowing of skin, whites of the eyes and mucous membranes

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

- nausea and diarrhoea

Side effects with unknown frequency

- serious skin conditions (Stevens-Johnson Syndrome) with symptoms like a rash, fever, or other flu-like symptoms such as fever, sore throat, and fatigue. Within a few days, a painful rash appears on the skin, often starting on the face and spreading to other parts of the body after starting a new medication or during an illness; severe skin condition with rash that is more widespread. Large areas of the skin may detach and peel off, resembling a severe burn or major skin injury (Toxic Epidermal Necrolysis (TEN)
- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug induced hypersensitivity syndrome (DIHS), which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs. See also section 2
- an acute pustular eruption characterised by the sudden onset of numerous small pus-filled blisters on reddened skin, which can occur all over the body or in specific areas (AGEP). Symptoms such as fever, skin peeling, itchiness, face and extremity swelling, nail/hair changes and mucous membrane involvement may occur
- development of one or more red or pinkish circular or oval-shaped areas (flat or with defined borders) on the skin as a result of systemic exposure to a medicine (FDE).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF INTRAMOL

Store at or below 30 °C. Protect from light. Do not refrigerate or freeze.

Single use only, discard any remaining portion.

Store the bottle in the outer carton until required for use.

Use immediately after opening.

Do not use the bottle if the plastic bag is missing or tampered with.

Do not administer if the solution contains any visible particulate matter.

KEEP INTRAMOL OUT OF SIGHT AND REACH OF CHILDREN.

7. PRESENTATION OF INTRAMOL

INTRAMOL is presented in transparent 100 ml low density polyethylene (LDPE) bottles sealed with a white, low density polyethylene (LDPE) cap. The bottle is packed in an outer polyethylene bag in an outer cardboard carton.

8. IDENTIFICATION OF INTRAMOL

INTRAMOL infusion (1 % *w/v*) is in the form of sterile infusion solution. The product is clear colourless to yellowish solution, free of visible particulate matter.

9. REGISTRATION NUMBER

47/2.7/0570

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Azinga Pharmaceuticals (Pty) Ltd.

100 Sovereign Road

Route 21 Corporate Park

Nellmapius Drive

Irene

Tel: (012) 345 1747

11. DATE OF LAST REVISION

29 September 2023