



ANTALGINE

INJECTABLE SOLUTION

COMPOSITION

Metamizole (i.f. sodium monohydrate).....	46.3 (50.00g*)
*1 g of metamizole base corresponds to 1.08 g of metamizole sodium monohydrate.	
Excipient q.s.to.....	100 ml

PHARMACEUTICAL PROPERTIES

Metamizole (dipyrone) is an NSAID of the pyrazole family, with mainly analgesic and antipyretic properties. It is considered a powerful non-morphine analgesic. It also has moderate anti-inflammatory and antispasmodic effects. The analgesic effect results from its action at the level of the pain nerve centers. Thanks to its antipyretic actions, **Metamizole** accelerates the return to a normal state during painful febrile and inflammatory syndromes. Its spasmolytic effect is due to its action on smooth muscle fibers. This action is accompanied by a vasodilator effect, which simultaneously ensures a better irrigation of the affected areas.

The maximum plasma concentration (C_{max}) appears 1 hour after intramuscular administration.

In general, **metamizole** is not detected in plasma due to its first pathway through the liver and/or the digestive tract, which results in its total metabolism into several metabolites. The most active of these metabolites is 4-methylaminoantipyrine (4-MAA). This main and primary metabolite as well as other secondary ones are weakly bound to plasma proteins (58% for 4-MAA).

The volume of distribution of 4-MAA in horses is approximately 1.85 L/kg. The major route of metabolism is acetylation, which is mediated by cytochrome P450-dependent enzymes. This biotransformation pathway has allowed the distinction between slow and fast acetylators in humans. Acetylated and demethylated 4-MAA undergoes a second reaction of sulfo- or glucuro-conjugation before its excretion. The latter is mainly done by urinary route (90% of the administered dose is eliminated by the kidney). 4-MAA and its metabolites are also excreted by the milk route. In horses, the elimination half-life of 4-MAA after intravenous administration is on average 4.85 hours.

TARGET SPECIES

Cattle, horses, dogs and cats.

INDICATIONS

Reduction of pain of visceral origin, especially when associated with spasms.

ADMINISTRATION AND DOSAGE

Routes of administration: strict slow intravenous, intramuscular.

The intravenous route is recommended for urgent procedures.

For intramuscular injections, it is preferable to distribute the total dose in several points.

Dosage :

- **Horses:** 23 to 46 mg of metamizole per kg of body weight, corresponding to 5 to 10 ml of solution per 100 kg body weight.
- **Cattle:** 23 mg of metamizole per kg of body weight, corresponding to 5 ml of solution per 100 kg body weight.
- **Dogs, cats:** 92.6 mg to 185.2 mg of metamizole per kg of body weight, corresponding to 1 ml of solution per 2.5 to 5 kg of body weight.

The effect of the product starts 5 to 10 minutes after the injection and lasts for about 1 hour. If the pain and agitation of the animal reappear after the product has worn off, the injection can be repeated.

In case of multiple repeat injections of the product, long-acting metabolites will accumulate and the dosage should be reduced accordingly.

CONTRAINDICATIONS AND INTERACTIONS

- Do not use in the following conditions :
 - Hematopoietic lesions;
 - Gastrointestinal ulceration or chronic gastrointestinal disorders;
 - Renal insufficiency;
 - Asthma.
- Do not use in cases of hypersensitivity.
- Not recommended for use in pregnant females.
- Do not use in combination with uric barbiturates, glucocorticoids, neuroleptics, diuretics, phenylbutazone or chlorpromazine.

SIDE EFFECTS

- Cardiovascular shock in case of too rapid intravenous injection.
- Irritation, intestinal hemorrhage, renal failure.
- **In dogs:** Local reactions at the injection site and splenomegaly.
- **In cats:** Hyper-salivation, lethargy.

PRECAUTIONS FOR USE

In animals:

- Injection of the solution may produce irritation of the subcutaneous tissue, but without necrosis or suppuration. Therefore, intramuscular injections must be performed under strict aseptic conditions.

In the person administering the veterinary drug to the animals:

- In case of accidental self-injection, seek medical advice immediately and show the leaflet or labeling.

SPECIFIC WARNINGS FOR EACH TARGET SPECIES

- **In horses**, this product can induce a positive reaction during anti-doping tests.

WITHDRAWAL PERIOD

Cattle:

- **Meat and offal:** 18 days.
- **Milk:** in the absence of a milk withdrawal time, it is preferable not to use the product in lactating females or in future milk producing females up to 2 months before parturition.

Horses:

- **Meat and offal:** 15 days.
- **Milk:** in the absence of a milk withdrawal time, it is preferable not to use the product in lactating females or in future milk producing females up to 2 months before parturition.

STORAGE CONDITIONS

- **Unopened container:** Keep product in original packaging, away from light and at a temperature ≤ 25 °C..
- **After opening the bottle:** 4 weeks.

PHARMACEUTICAL FORM AND PRESENTATION

Solution for injection.

Bottles of 50 ml and 100 ml.