

Summary of Product Characteristics

1 Name of the medicinal product

TASA WFI

2 Qualitative and quantitative composition

Each ml contains 100% Water for Injections

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Solvent for parenteral use

4 Clinical particulars

4.1 Therapeutic indications

Water for Injections BP is indicated to be used as a solvent for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Posology

The dosage administered will be dictated by the nature of the additive used. The administration rate will be dependent upon the dose regimen of the prescribed drug.

Following suitable admixture of prescribed additives, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. The solution should only be used if it is clear without visible particles.

Method of administration

For parenteral use.

The directions for use will be dependent upon the appropriate medicinal product to which this solvent is added, which will dictate the appropriate volumes as well as administration route.

4.3 Contraindications

Water for Injections should not be administered alone because it may cause haemolysis.

The contraindications related to the added medicinal product should be considered.

4.4 Special warnings and precautions for use

Water for Injections is hypotonic and should not be administered alone as it may cause hemolysis.

4.5 Interaction with other medicinal products and other forms of interaction

The possible clinical interactions between the different medicinal products to be dissolved should be considered.

4.6 Fertility, pregnancy and lactation

The risks during use are determined by the nature of the added medicinal products.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

May cause haemolysis if administered alone.

The nature of the additive will determine the likelihood of any other undesirable effects.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose

No effects are anticipated if used as instructed.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using water for injections as a diluent.

The signs and symptoms of overdose will also be related to the nature of the medicinal product being added. In the event of accidental overdose, the treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the medicinal product administered.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and Diluting Agents.

ATC code: VO7AB.

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacodynamics will depend on the nature of the drug added.

5.2 Pharmacokinetic properties

Water for Injections being only the vehicle for the administration of the added medicinal product, the pharmacokinetics will depend on the nature of the drug added.

5.3 Preclinical safety data

Water for Injections being only the vehicle for the administration of the added medicinal product, the preclinical safety data for the solutions in use will depend on the nature of the drug added.

6 Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

None Known.

6.3 Shelf life

Shelf life 2 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Bag sizes: 50ml, 100ml, 250ml, 500ml, 1000 mL or 2000ml.

The bags are overwrapped with a protective tri-laminate pouch.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Tasa Pharma Limited
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8. Marketing authorization number

H2022/CTD9287/20833

9. Date of first registration

16/03/2023

10. Date of revision of the text:

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