SPC

Country:	Lebanon
Date of approval:	13.05.2010
Procedure:	National

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
WATER FOR INJECTIONS PROAMP, solvent for parenteral formulations

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Water for injections .....qs 1 ampoule

One 5 ml ampoule contains 5 g of water for injections.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Solvent for parenteral formulations.
Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
This sterile water for injections PROAMP is used as a vehicle for the dilution and reconstitution of pharmaceutical products for parenteral administration.

4.2. Posology and method of administration

Posology
The dosage of the reconstituted preparation is dictated by the nature of the substance added. The speed of administration will depend on the drug regimen prescribed.
After incorporation of the prescribed additives, the dosage generally depends on the age, weight and medical condition of the patient and on his/her laboratory test results.

Method of administration
This solution is intended for the dilution of medicinal products for administration. The instructions for use applicable to the product added will determine the appropriate volumes and the route of administration.

4.3. Contraindications
Water for injections must not be administered on its own.
Any contraindications linked to the pharmaceutical product added must be taken into account.

4.4. Special warnings and precautions for use
Water for injections is hypotonic and should not be injected on its own.
Do not use as an intravenous injection without using a suitable solution to achieve a near-isotonic state.
When water for injections is used as a diluent for hypertonic solutions, a suitable dilution must be carried out in an attempt to achieve isotonicity.
Haemolysis may occur after the infusion of large amounts of hypotonic solutions in which water is used as a diluent for injectable medications.
When administering large volumes, ionic balance must be checked regularly.
The high-volume pack sizes are intended for use as a raw material for dilutions performed while preparing pharmaceutical products. They are not directly intended for intravenous administration.

4.5. Interaction with other medicinal products and other forms of interaction
None known.
Any possible drug interactions of the medicinal products to be dissolved must be taken into consideration.

4.6. Pregnancy and lactation
Any risks during pregnancy and breast-feeding are linked to the nature of the substances added.

4.7. Effects on ability to drive and use machines
Not relevant.

4.8. Undesirable effects
The intravenous injection of water for injections causes haemolysis when injected on its own.
The nature of the product added will determine the likelihood of other undesirable effects.

4.9. Overdose
Haemolysis may occur after the infusion of large amounts of hypotonic solutions in which water is used as a diluent for injectable medications.
The signs and symptoms of an overdose are also related to the kind of medicinal product added.
In the event of accidental overdose, treatment should be discontinued and the patient should be assessed for signs and symptoms related to the medicinal product administered.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: SOLVENT AND DILUENT
ATC code: V07AB

Since water for injections is only a vehicle for the administration of a medicinal product, the pharmacodynamic properties depend on the kind of medicinal product added.

5.2. Pharmacokinetic properties
Since water for injections is only a vehicle for the administration of a medicinal product, the pharmacokinetic properties depend on the kind of medicinal product added.

5.3. Preclinical safety data
Since water for injections is only a vehicle for the administration of a medicinal product, the preclinical safety data depend on the kind of medicinal product added.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Not relevant.

6.2. Incompatibilities
Before dissolving a medicinal product, check its solubility and/or stability in water.
In the case of a mixture of several active substances, check their mutual compatibility.

6.3. Shelf life
2 years for the 5 ml ampoules.

6.4. Special precautions for storage
Store below 25°C.

6.5. Nature and contents of container
5, in ampoules (polypropylene), box of 10, 20, 50 or 100.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling
Not relevant.