PHARMA INNOVA CO., LTD.
1/38 Moo 4, Liebkhlong 7 Road, Buengkamproi, Lam Luk Ka, Pathumthani 12150, Thailand
Tel. (662) 971-5335, Fax (662) 971-5470 E-mail: pharma@pharmainnova.co.th

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 Product Name

SWI EZ/USE

1.2 Strength

Each mL contains:

Water for injection	1 mL

1.3 Pharmaceutical Dosage Form

Solution for injection

2. Qualitative and quantitative composition

Each mL contains:

Water for injection	1 mL

3. Pharmaceutical form

Sterile solution

4. Clinical particulars

4.1 Therapeutic indications

To be used as a vehicle 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.

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

SWI EZ/USE should not be administered alone because it may cause haemolysis. The contraindications related to the added medicinal product should be considered.

4.4 Special warning and precautions for use

SWI EZ/USE is hypotonic and it should not be administered alone, because it may cause haemolysis.

4.5 Interactions with other medicinal products and other forms of interactions

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

4.6 Pregnancy and lactation

May be used during 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 relevant.

4.8 Undesirable effects

May cause haemolysis if administered alone.

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

4.9 Overdose

No effects are anticipated if used as instructed.

Haemolysis may occur following infusion of large volumes of hypotonic solutions using SWI EZ/USE as 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, including irrigating solutions, ATC code: V07AB.

SWI EZ/USE 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

SWI EZ/USE 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

SWI EZ/USE being only the vehicle for the administration of the added medicinal product, the preclinical safety data will depend on the nature of the drug added.

6. Pharmaceutical particulars

6.1 List of excipients

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6.2 Incompatibilities

SWI EZ/USE should not be mixed with any other agents unless their compatibility has been established.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Prefilled Syringe (PFS) of 3, 5, 10 and 20 mL, individually packed or unpacked in plastic sachet.

Packed or unpacked in a paper box of 10, 20, 50, 100 and 200 sachets.

7. Marketing authorisation holder

PHARMA INNOVA COMPANY LIMITED

1/38 Moo 4, Liebkhlong 7 Road, Buengkamproi,

Lam Luk Ka, Pathumthani 12150, Thailand

Tel. (662) 971-5335 FAX (662) 971-5470

8. Marketing authorisation number(s)

xx xxx/xx

9. Date of first authorization/ renewal of the authorization

DD/MM/YYYY

10. Date of revision of the text

5 April 2022