

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections solvent for parenteral use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 vial contains 2, 2.5, 3, 4, 5, 5.6, 10, 15, 20, 40 or 50ml Water for Injections

3 PHARMACEUTICAL FORM

Solvent for parenteral use
Clear, colourless liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use as a solvent for reconstitution of suitable medicinal products for parenteral use

4.2 Posology and method of administration

Dosage and method of administration depend on the instructions given for the medicinal product to be dissolved or diluted.

4.3 Contraindications

Do not administer Water for Injections on its own

4.4 Special warnings and precautions for use

Water for Injections is hypotonic and it should not be administered alone

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 Fertility, pregnancy and lactation

None

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

None

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance Section, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;
Fax: +353 1 6762517; website: www.hpra.ie; Email: medsafety@hpra.ie

4.9 Overdose

None

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Solvent and diluting agent

ATC code: V07AB

Pharmacodynamics: Not applicable

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Not applicable

6.2 Incompatibilities

For possible interactions and incompatibilities check Summary of Product Characteristics and Package Information Leaflet of the medicinal product which is intended to be reconstituted with Water for Injections.

Those medicinal products known to be incompatible with Water for Injections must not be used.

6.3 Shelf life

2.5, 3, 4, 5, 5.6, 10, 15, 20, 40, 50 ml: 5 years

2 ml: 30 months

After opening, the product must be used immediately.

For in use shelf life, after reconstitution of the medicinal product, check Summary of Product Characteristics and Package Information Leaflet of the medicinal product which was reconstituted with Water for Injections.

6.4 Special precautions for storage

Do not freeze.

This medicinal product does not require any special storage conditions.

For storage conditions after first opening and reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Pack sizes (1 vial per pack)	Container details
2ml, 2.5 ml, 3 ml, 4 ml, 5 ml	<p>In 6 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc.</p> <p><u>For the filling size:</u></p> <p>2 ml (overage 0.3 ml): Blue/ purple, 2.5 ml (overage 0.3 ml): Blue/ blue, 2.5 ml (overage 0.4 ml): Blue/ lime,</p>

	2.5 ml (overage 0.6 ml): Blue/ light blue, 3 ml (overage 0.4 ml): Blue/ orange, 4 ml (overage 0.3 ml): Blue/ grey, 5 ml (overage 0.4 ml): Blue/ green.
5.6 ml, 10 ml	In 10 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc. <u>For the filling size:</u> 5.6 ml (overage 0.46 ml): Blue/ lime, 10 ml (overage 0.5 ml): Blue/ blue.
15 ml	In 15 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc. <u>For the filling size:</u> 15 ml (overage 0.5 ml): Blue/ blue.
20 ml	In 25 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc. <u>For the filling size:</u> 20 ml (overage 1 ml): Blue/ blue.
40 ml, 50 ml	In 50 ml injection vial clear glass with chlorobutyl or bromobutyl rubber stopper and aluminium crimp-cap with polypropylene plastic disc. <u>For the filling size:</u> 40 ml (overage 1.5 ml): Blue/ blue 50 ml (overage 2 ml): Blue/ blue.
Not all pack sizes may be marketed.	

6.6 Special precautions for disposal and other handling

- Discard after single use.
- Use only if the Water for Injections is clear, colourless, without visible particles and if the container is undamaged.
- Reconstitution and withdrawal must be carried out under aseptic conditions.
- Any unused solution should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

CSL Behring GmbH
Emil-von-Behring-Strasse 76
35041 Marburg
Germany

8 MARKETING AUTHORISATION NUMBER

PA0800/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2019
Date of last renewal 1st November 2023

10 DATE OF REVISION OF THE TEXT

July 2024
19 July 2024