

Water for injections solvent for parenteral use

Water for injections

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4..

What is in this leaflet

1. What Water for injections is and what it is used for
2. What you need to know before you use Water for injections
3. How to use Water for injections
4. Possible side effects
5. How to store Water for injections
6. Contents of the pack and other information

1. What Water for injections is and what it is used for

Water for Injections is pure, sterile water. It is used to dilute medicines before use. For example medicines that are given by:

- injection (given using a needle, for example into your vein)
- infusion (slow injection) into a vein, also called a 'drip'.

2. What you need to know before you use Water for injections Do not use Water for injections:

You must NOT receive Water for injections on its own. If injected into your bloodstream on its own it can cause your red blood cells to take in water and burst (haemolysis). This is because Water for injections does not have the same consistency as your blood.

Water for injections will always be mixed with one or more medicines by a healthcare professional before you receive it.

You should read the Patient Information Leaflet of your medicine or medicines that are being mixed with Water for injections. These will tell you whether or not you can receive the solution.

Warnings and precautions

Talk to your doctor or pharmacist before using Water for injections.

Water for injections should not be used on its own. Before you use Water for injections:

- it will always be mixed with one or more medicines
- your healthcare professional will make sure that the mixture is roughly the same consistency as your blood (isotonic). Depending on the type of medicine you are given, this will mean that:
- the medicine needs to be diluted with Water for injections
- another substance needs to be added to your mixture of Water for injections and medicine before use.

You will be more likely to suffer haemolysis if you are given large volumes of hypotonic solutions of Water for injections (solutions that are not as concentrated as your blood).

To help preventing this, your doctor will take a blood sample to monitor the balance of the chemicals in your blood (the ionic balance).

Before you are given medicines mixed with Water for injections your doctor will check that:

- the medicines are stable in Water for injections
- the medicines will not interact with each other

Other medicines and Water for injections

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The medicines you are using mixed with Water for injections may interact with each other.

Water for injections with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Any risk to your unborn baby or your pregnancy will depend on which medicines you are using mixed with Water for injections.

Any risk to your baby during breast-feeding will also depend on which medicines you are using mixed with Water for injections.

Your doctor will be able to advise you on what risks are involved in taking particular medicines.

Your doctor will only give you medicines during pregnancy or breast-feeding if it is essential.

Driving and using machines

Water for injections does not affect your ability to drive or use machines.

Any effects on your ability to drive or use machines will depend on which medicines you are using mixed with Water for injections. Your doctor will be able to advise you on this.

3. How to use Water for injections

Water for Injections will be given to you by a doctor or nurse.

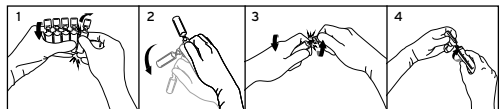
Your doctor will decide on how much you need and when and how it is to be given. This will depend on which medicine or medicines you need to take with Water for Injections.

Your doctor will also consider your age, weight, condition and what other treatments you are receiving.

You should NOT be given Water for Injections if there are particles floating in the water or if the pack is damaged in any way.

Handling instructions:

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2). To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the luer-syringe or luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

If you receive more Water for injections than you should:

If you are given too much Water for Injections (over-infusion) this may lead to haemolysis. Haemolysis is when your red blood cells take in water and burst.

The medicines mixed with Water for Injections may also cause symptoms if administered in too large quantities (over-infusion). Any signs and symptoms of overdose will depend on which medicines you are using mixed with Water for Injections.

If you are accidentally given an overdose your treatment will be stopped and you will be given treatment depending on the symptoms.

You should read the Patient Information Leaflet of the medicines mixed with Water for Injections for a list of possible symptoms of over-infusion.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Water for injections can cause side effects, although not everybody gets them.

You may suffer bursting (haemolysis) of your red blood cells if:

- you use Water for Injections on its own
- Water for Injections is used to make solutions for injection or infusion that are not of a similar consistency to your blood (isotonic).

If a medicine has been added to Water for Injections, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

If you notice any side effects or are concerned about anything, please tell your doctor or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

For Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store Water for injections

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Keep the ampoule in the outer carton.

Do not use this medicine after the expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.

Once the pack is opened Water for injections should be used straight away.

6. Contents of the pack and other information

What Water for injections contains

The only active ingredient is sterile water for injections. Each presentation contains 100% sterile water for injections.

What Water for injections looks like and contents of the pack

Water for injections is a clear solution, free from visible particles and it is presented as the following formats:

Package with 20 ampoules containing 5 ml
Package with 50 ampoules containing 5 ml
Package with 20 ampoules containing 10 ml
Package with 50 ampoules containing 10 ml
Package with 20 ampoules containing 20 ml
Package with 1 bottle containing 500 ml
Package with 10 bottles containing 500 ml
Package with 1 bottle containing 1000 ml
Package with 10 bottles containing 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Fresenius Kabi Limited,
Cestrian Court,
Eastgate Way,
Manor Park,
Runcorn,
Cheshire,
WA7 1NT
United Kingdom

Manufacturer:

FRESENIUS KABI ESPAÑA, S.A.
C/ Marina, 16-18, planta 17
08005-Barcelona (SPAIN)

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Water voor injecties Fresenius Kabi
Czech Republic	Water for Injection Kabi
Estonia	Water for injections Kabi
Greece	Water For Injection Kabi, Διαλύτης για ενέσιμα μικρού όγκου (<50ml).
Hungary	Infekcióhoz való víz Kabi
Ireland	Water for injections solvent for parenteral use
Latvia	Water for injections Kabi
Lithuania	Water for injections Kabi
The Netherlands	Water voor injecties Fresenius Kabi
Poland	Aqua pro iniectione Kabi
Romania	Apă pentru preparate injectabile Kabi, solvent pentru uz parenteral
Slovakia	Water for Injection Kabi
Slovenia	Voda za injekcije Fresenius Kabi vehikel za parenteralno uporabo
Spain	Agua para inyección Meinsol, disolvente para uso parenteral

This leaflet was last approved in 03/2015

The following information is intended for medical or health-care professionals only:

Handling and Preparation

Use only if the solution is clear, without visible particles and if the container is undamaged.

Water for Injections should not be infused alone.

The infusion should be made isotonic prior to parenteral administration.

Solutions containing additives should be used immediately and not stored.

Discard after single use.

Discard any unused portion.

In-use shelf-life: Additives

Chemical and physical stability of any additive at the pH of Water for Injections (4.5 to 7.0) in the container should be established prior to use.

From a microbiological point of view, the diluted product should be used immediately, unless reconstitution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Incompatibilities of additive medications

As with all parenteral solutions, before adding medications, compatibility of these additives with the solution must be assessed.

The Instructions for Use of the medicinal product to be added must be consulted.

Before adding a medicinal product, verify it is soluble and stable in water at the pH of Water for Injections (4.5 to 7.0)

Water for injections
(Irlanda)
BP8

Colour: Black

Size: 148 x 210 mm

Fonts size: 12/6,5 pt

13.5.2015

Correction: 2

Version: 00

Water for injections solvent for parenteral use

Water for injections

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4..

What is in this leaflet

1. What Water for injections is and what it is used for
2. What you need to know before you use Water for injections
3. How to use Water for injections
4. Possible side effects
5. How to store Water for injections
6. Contents of the pack and other information

1. What Water for injections is and what it is used for

Water for Injections is pure, sterile water. It is used to dilute medicines before use. For example medicines that are given by:

- injection (given using a needle, for example into your vein)
- infusion (slow injection) into a vein, also called a 'drip'.

2. What you need to know before you use Water for injections Do not use Water for injections:

You must NOT receive Water for injections on its own. If injected into your bloodstream on its own it can cause your red blood cells to take in water and burst (haemolysis). This is because Water for injections does not have the same consistency as your blood.

Water for injections will always be mixed with one or more medicines by a healthcare professional before you receive it.

You should read the Patient Information Leaflet of your medicine or medicines that are being mixed with Water for injections. These will tell you whether or not you can receive the solution.

Warnings and precautions

Talk to your doctor or pharmacist before using Water for injections.

Water for injections should not be used on its own. Before you use Water for injections:

- it will always be mixed with one or more medicines
- your healthcare professional will make sure that the mixture is roughly the same consistency as your blood (isotonic). Depending on the type of medicine you are given, this will mean that:
- the medicine needs to be diluted with Water for injections
- another substance needs to be added to your mixture of Water for injections and medicine before use.

You will be more likely to suffer haemolysis if you are given large volumes of hypotonic solutions of Water for injections (solutions that are not as concentrated as your blood).

To help preventing this, your doctor will take a blood sample to monitor the balance of the chemicals in your blood (the ionic balance).

Before you are given medicines mixed with Water for injections your doctor will check that:

- the medicines are stable in Water for injections
- the medicines will not interact with each other

Other medicines and Water for injections

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The medicines you are using mixed with Water for injections may interact with each other.

Water for injections with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Any risk to your unborn baby or your pregnancy will depend on which medicines you are using mixed with Water for injections.

Any risk to your baby during breast-feeding will also depend on which medicines you are using mixed with Water for injections.

Your doctor will be able to advise you on what risks are involved in taking particular medicines.

Your doctor will only give you medicines during pregnancy or breast-feeding if it is essential.

Driving and using machines

Water for injections does not affect your ability to drive or use machines.

Any effects on your ability to drive or use machines will depend on which medicines you are using mixed with Water for injections. Your doctor will be able to advise you on this.

3. How to use Water for injections

Water for Injections will be given to you by a doctor or nurse.

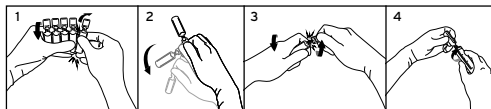
Your doctor will decide on how much you need and when and how it is to be given. This will depend on which medicine or medicines you need to take with Water for Injections.

Your doctor will also consider your age, weight, condition and what other treatments you are receiving.

You should NOT be given Water for Injections if there are particles floating in the water or if the pack is damaged in any way.

Handling instructions:

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2). To open the ampoule, twist the ampoule body and the ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the luer-syringe or luer-lock syringe as shown in figure (4).



Therefore, no needle is needed to extract the solution. Extract the liquid.

If you receive more Water for injections than you should:

If you are given too much Water for Injections (over-infusion) this may lead to haemolysis. Haemolysis is when your red blood cells take in water and burst.

The medicines mixed with Water for Injections may also cause symptoms if administered in too large quantities (over-infusion). Any signs and symptoms of overdose will depend on which medicines you are using mixed with Water for Injections.

If you are accidentally given an overdose your treatment will be stopped and you will be given treatment depending on the symptoms.

You should read the Patient Information Leaflet of the medicines mixed with Water for Injections for a list of possible symptoms of over-infusion.

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Water for injections can cause side effects, although not everybody gets them.

You may suffer bursting (haemolysis) of your red blood cells if:

- you use Water for Injections on its own
- Water for Injections is used to make solutions for injection or infusion that are not of a similar consistency to your blood (isotonic).

If a medicine has been added to Water for Injections, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Patient Information Leaflet of the added medicine for a list of possible symptoms.

If you notice any side effects or are concerned about anything, please tell your doctor or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

For Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store Water for injections

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Keep the ampoule in the outer carton.

Do not use this medicine after the expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.

Once the pack is opened Water for injections should be used straight away.

6. Contents of the pack and other information

What Water for injections contains

The only active ingredient is sterile water for injections. Each presentation contains 100% sterile water for injections.

What Water for injections looks like and contents of the pack
Water for injections is a clear solution, free from visible particles and it is presented as the following formats:

Package with 20 ampoules containing 5 ml
Package with 50 ampoules containing 5 ml
Package with 20 ampoules containing 10 ml
Package with 50 ampoules containing 10 ml
Package with 20 ampoules containing 20 ml
Package with 1 bottle containing 500 ml
Package with 10 bottles containing 500 ml
Package with 1 bottle containing 1000 ml
Package with 10 bottles containing 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Fresenius Kabi Limited,
Cestrian Court,
Eastgate Way,
Manor Park,
Runcorn,
Cheshire,
WA7 1NT
United Kingdom

Manufacturer:

FRESENIUS KABI ESPAÑA, S.A.
C/ Marina, 16-18, planta 17
08005-Barcelona (SPAIN)

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Water voor injecties Fresenius Kabi
Czech Republic	Water for Injection Kabi
Estonia	Water for injections Kabi
Greece	Water For Injection Kabi, Διαλύτης για ενέσιμα μικρού όγκου (<50ml).
Hungary	Infekcióhoz való víz Kabi
Ireland	Water for injections solvent for parenteral use
Latvia	Water for injections Kabi
Lithuania	Water for injections Kabi
The Netherlands	Water voor injecties Fresenius Kabi
Poland	Aqua pro iniectione Kabi
Romania	Apă pentru preparate injectabile Kabi, solvent pentru uz parenteral
Slovakia	Water for Injection Kabi
Slovenia	Voda za injekcije Fresenius Kabi vehikel za parenteralno uporabo
Spain	Agua para inyección Meinsol, disolvente para uso parenteral

This leaflet was last approved in 03/2015

The following information is intended for medical or health-care professionals only:

Handling and Preparation

Use only if the solution is clear, without visible particles and if the container is undamaged.

Water for Injections should not be infused alone.

The infusion should be made isotonic prior to parenteral administration.

Solutions containing additives should be used immediately and not stored.

Discard after single use.

Discard any unused portion.

In-use shelf-life: Additives

Chemical and physical stability of any additive at the pH of Water for Injections (4.5 to 7.0) in the container should be established prior to use.

From a microbiological point of view, the diluted product should be used immediately, unless reconstitution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Incompatibilities of additive medications

As with all parenteral solutions, before adding medications, compatibility of these additives with the solution must be assessed.

The Instructions for Use of the medicinal product to be added must be consulted.

Before adding a medicinal product, verify it is soluble and stable in water at the pH of Water for Injections (4.5 to 7.0)

**Water for injections
(Irlanda)**

BP9

Colour: Black

Size: 148 x 210 mm

Size folding: 50 x 210 mm

Fonts size: 12/6,5 pt

13.5.2015

Correction: 1

Version: 00