First in the USA in plastic pre-filled syringe

Sterile Water for Injection, USP

Benefits and Features

- Ready-to-use prefilled syringe for diluting or dissolving drugs
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Not made with natural rubber latex, DEHP, or PVC
- Luer Lock syringe compatible with Luer-Activated IV Systems
- Reduce injectable compounding steps
- AP rated
- Bar Coded
- No Preservatives

SKU(s) in Product Family

UoS† NDC	Product #	Fill Volume	Unit / BX	Bar Coded
64253-0020-30	MIW-2030	10 mL	60	√
64253-0020-91	02091	10mL	10	√

Wholesalers Item Number

UoS† NDC	AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
64253-0020-30	10237367	5659065	2315257	1172488	905752
64253-0020-91	10257591	5716808	1569102	1179480	021204

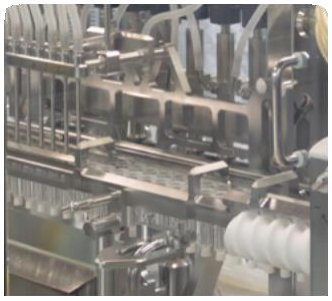
To learn more about Medefil's Sterile Water for Injection, USP please visit our website at www.medefilinc.com, call (630) 682-4600, or via email at: info@medefilinc.com

Sterile Water for Injection, USP

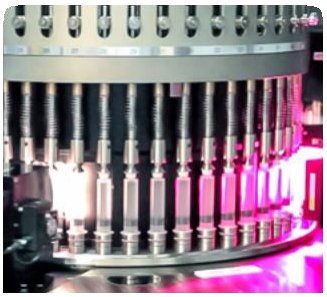
About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has a state-of-the-art scientific research infrastructure and high-quality manufacturing capabilities leading to effective execution of development and product supply.

State-of-the-art Manufacturing



Filling



Inspection

Labeling

Packaging

Important Safety Information

WARNINGS:
Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

PRECAUTIONS:
Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.
Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C. Animal reproduction studies have not been conducted with Sterile Water for Injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS:
Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE:
Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See **WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS.**

To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc. at 1-630-682-4600 or www.medefilinc.com or FDA at
1-800-FDA-1088 or www.fda.gov/medwatch.

For complete prescribing information, refer to the package insert.

MEDEFIL, INC.
250 Windy Point Drive
Glendale Heights Illinois 60139
Phone (630) 682-4600 | Fax (630) 682-9100 | www.medefilinc.com

MED-12-005; Rev 002.