

Sympfyny® Instructions for Use

Purpose of Medical Device: Oral Multiparticulate Drug Delivery Device. Exclusively for clinical investigation.











Read and follow instructions completely prior to using the device. Failure to follow instructions may result in delivery of incorrect dose. Carefully follow instructions.

DO NOT USE device if device appears damaged or broken. Contact Röchling Medical Neuhaus at +49 3679 72606-0 or your healthcare provider for a replacement device.

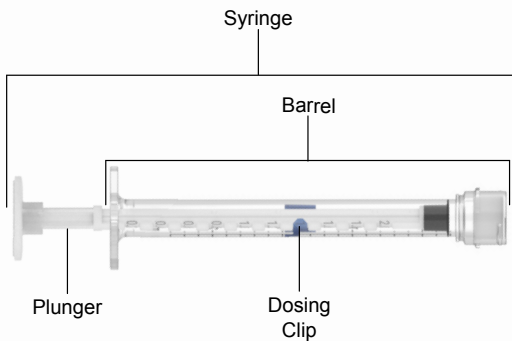
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority. Contact Röchling Medical Neuhaus at +49 3679 72606-0.

Latest revision of instructions for use: 2019-12-16

Warnings and Precautions:

-  Do not overfill syringe when filling with medication, overfilling can result in overdose.
-  Do not fill device with anything other than multiparticulate drugs prescribed by a doctor.
-  Do not use the syringe for any other purpose then to deliver oral multiparticulate medication.
-  Visually inspect all components for damage before use.
-  Do not use device that appears broken or damaged. 
-  Make sure syringe is dry before filling.
-  Do not attempt to push medication back into bottle.

Sympfify Components:



Bottle

Storage and Handling Conditions:

Store device with medication in a safe, clean area.



Store syringe with plunger in barrel (make sure its not sticking out).

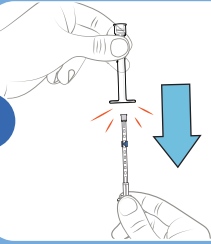


Store device away from heat.

Follow storage conditions of medication on bottle label.

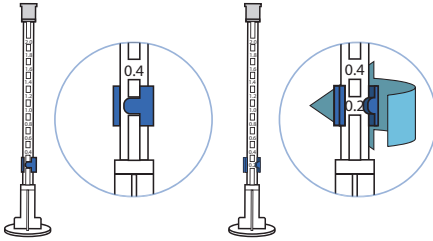
Set Dose:

1



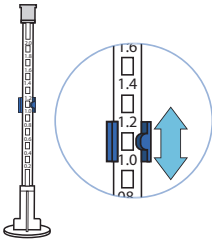
Pull the plunger from the barrel to reveal the dosing clip. There will be resistance, pull past this.

2



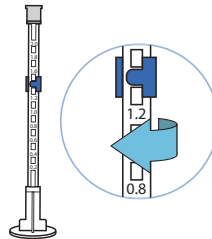
Turn the dosing clip counter-clockwise to unlock.

3



Slide the clip to desired dose.

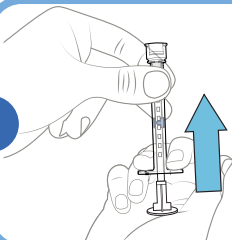
4



Turn dosing clip clockwise to set new dose amount.

***Note:** The selected dose amount will be covered when the clip is locked in place .

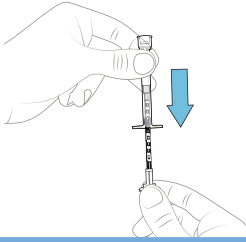
5



Forcefully re-insert the plunger into the barrel. The syringe is now ready for use.

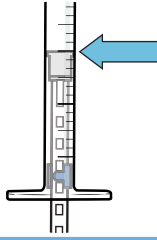
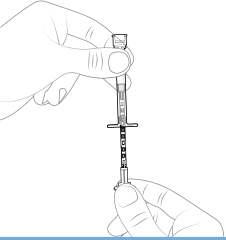
Filling and Dispensing:

6



Pull the plunger back until it stops. Plunger head will align with desired dose marking on barrel.

7



Confirm syringe is set to correct dose prior to filling with medication.

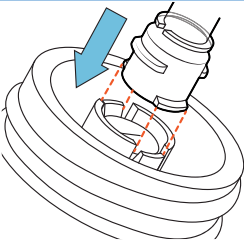
8



Remove bottle cap by pressing down and turning.

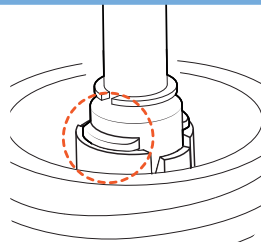
Hold the syringe around barrel.

9



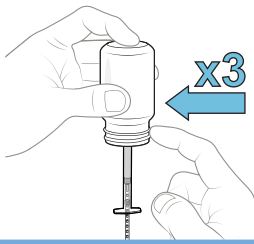
Insert syringe onto the bottle by aligning the tabs on the syringe tip with the tab slots on the bottle.

10



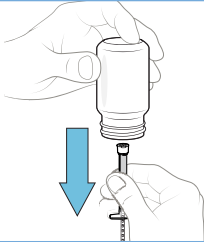
Syringe is in place when you can no longer push barrel into bottle.

11



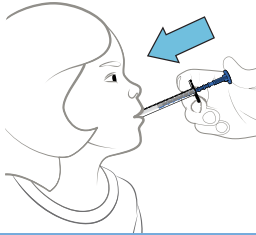
Flip the bottle vertically and tap the bottleneck 3 times to fill the syringe with drug.

12



In a vertical position hold barrel of syringe and remove syringe from bottle.

13



Depress the plunger inside the child's mouth to deliver the drug.

**Note: Can deliver drug to child's mouth in smaller amounts by depressing plunger part way.*

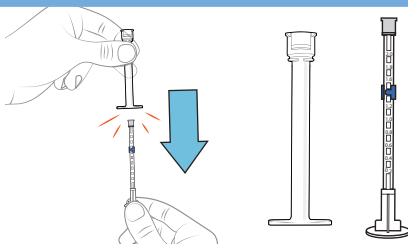
Maintenance: Clean syringe after each use

14



Rinse and dry the syringe tip with plunger fully depressed.

15



Remove the plunger from the barrel and allow to air dry for 1 hour before next use.

Verify Correct Installation:

Visual inspection of components (valve, dose markings, dose clip, etc.).

Check position of dosing clip to ensure it is placed over the number which matches the prescribed dose.

Disposal:



Dispose of device if you notice changes in performance or after **90** uses.

Dispose of device per local waste guidelines.

Material:

The medical device was manufactured with low density polyethylene (LDPE), polypropylene (PP), thermoplastic elastomer (TPE), and acrylonitrile butadiene styrene copolymer (ABS).

Dose Accuracy: +/- 10% per USP and EMA

Meets ISO7886-1 - Tolerance on graduations

The package obtained the Confirmation of Conformity after a formal test procedure ISO 8317 (2015). The package can be designated as child-resistant and suitable for adults.

 xxxxxx



Sympfyny® Manufacturing: Röchling Medical Neuhaus GmbH & Co. KG, Waldweg 16, 98724 Neuhaus am Rennweg/Germany