Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Humulin M3 KwikPen (mixture 3) 100 IU/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 100 IU insulin human (produced in E. coli by recombinant DNA technology).

One pre-filled pen contains 3 ml equivalent to 300 IU of biphasic isophane insulin – 30 % soluble insulin / 70 % isophane insulin.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

A suspension for injection in a pre-filled pen.

Product imported from Czech Republic:
Humulin M3 is a sterile suspension of human insulin in the proportion of 30 % soluble insulin to 70 % isophane insulin.

4 CLINICAL PARTICULARS

As per PA2276/006/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2276/006/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

m-cresol
glycerol
phenol
protamine sulfate
dibasic sodium phosphate
zinc oxide
water for injections.

The following may be used to adjust pH; hydrochloric acid and/or sodium hydroxide.

6.2 Incompatibilities

Humulin preparations should not be mixed with insulins produced by other manufacturers or with animal insulin preparations.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Unused pre-filled pens

Store in a refrigerator (2° C – 8° C). Do not freeze. Do not expose to excessive heat or direct sunlight.

After first use

Store below 30° C. Do not refrigerate. The pre-filled pen should not be stored with the needle attached.

6.5 Nature and contents of container

3 ml suspension in a cartridge (type I glass) with a plunger head at the bottom (rubber) and disc seal at the top (rubber) in a pre-filled pen. Pack size of 5.

6.6 Special precautions for disposal and other handling

Do not reuse needles. Dispose of the needle in a responsible manner. Needles and pens must not be shared. Humulin M3 KwikPen can be used until empty, then properly discard. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instruction for use and handling
To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed.

A suspension for injection in a pre-filled / disposable pen injector containing a 3ml cartridge. Humulin M3 KwikPen delivers up to 60 units per dose in single unit increments.

a) Preparing a dose

Humulin KwikPen containing Humulin M3 formulation should be rolled in the palms of the hands ten times and inverted 180° ten times immediately before use to resuspend the insulin until it appears uniformly cloudy or milky. If not, repeat the above procedure until contents are mixed. Cartridges contain a small glass bead to assist mixing. Do not shake vigorously as this may cause frothing, which may interfere with the correct measurement of the dose.

The cartridges should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or wall of the cartridge, giving a frosted appearance.

The cartridges are not designed to allow any other insulin to be mixed in the cartridge. Cartridges are not designed to be refilled.

Follow the instructions with Humulin M3 KwikPen for attaching the needle and administering the insulin injection.

For Humulin M3 KwikPen, a needle must always be attached before priming, dialing and injecting an insulin dose. Humulin M3 KwikPen should always be primed before each injection. Failure to prime Humulin M3 KwikPen may result in an inaccurate dose.

b) Injecting a dose

Inject the correct dose of insulin, as directed by your doctor or diabetes specialist nurse.
Use of the injection sites should be rotated so that the same is not used more than approximately once a month.

Each pack contains a patient information leaflet with instructions on how to inject insulin.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/501/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th May 2023

10 DATE OF REVISION OF THE TEXT