Mat-No./CAN/Datamatrix: xxxxxxx-xx (code is a sample)

Version/Revision index: 13

Date: 2021-10-08

Product code: 261 (A)
Product name: Octaplex
Country: Malaysia
Filling Size/Concentration: 500 IU

Format: 37 x 40 x 78 mm

Colours: Pantone 158 (40%-100%)

Black

Color-varnishfree

SPCK specification: ZMS_CAR_37x40x78

Design:

Satzstudio Borngräber octapharma®



Only in case of track and trace

variable data will be printed in black color on the final printed packaging material



Kementerian Kement

Lot AywwXzzz7 MAN 01/2035





octaplex®

Powder and solvent for solution for infusion

Human Prothrombin Complex, freeze-dried

Excipients: heparin, sodium citrate

This product contains substance of porcine source.

For intravenous injection after reconstitution with supplied solvent (20 ml Water for Injections).

Read the package leaflet before use. Single dose administration only. Use immediately after reconstitution.

Do not use turbid or incompletely dissolved solutions.

octaplex®

Powder and solvent for solution for infusion

Human Prothrombin Complex, freeze-dried

One	vial	contains:

XX-XXXXXX

Quantity Quantity per vial reconstitute solution

Total protein:

260–820 mg 13–41 mg/m Active substances Human coagulation factors II, VII, IX, X

Factor II 280-760 IU 14-38 IU/ml Factor VII 180-480 IU 9-24 IU/ml Factor IX 500 IU 25 IU/ml Factor X 360-600 IU 18-30 IU/ml

Protein C 260–620 IU 13–31 IU/ml
Protein S 240–640 IU 12–32 IU/ml

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Powder and solvent for solution for infusion

Human Prothrombin Complex, freeze-dried

Do not store above 25°C. Protect from light.

Do not freeze.

See package insert for

instructions for use.

Keep out of the reach of children. Jauhi dari kanak-kanak.

MAL20081743AZ

Controlled medicine.

octaplex®

Powder and solvent for solution for infusion

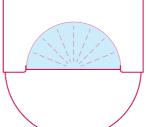
Human Prothrombin Complex, freeze-dried

Product Registration Holder: Pharmaniaga Marketing Sdn Bhd (198401005734) No 7, Lorong Keluli 1B, Kaw. Perindustrian Bukit Raja Selatan Seksyen 7, 40000 Shah Alam

Selangor Darul Ehsan, Malaysia

Manufactured by: OCTAPHARMA Pharmazeutika Produktionsges.m.b.H. Oberlaaer Strasse 235 A-1100 Vienna, Austria

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octa pharma.

Human Prothrombin Complex, freeze-dried Powder and solvent for solution for infusion







Mat-No./CAN/Datamatrix: xxxxxxx-xx (code is a sample)

07

Version/Revision index:

2021-09-15 Date:

Product code: 261 (A) Product name: Octaplex Country: Malaysia Filling Size/Concentration: 500 IU

Format: 153 x 40 x 78 mm

Pantone 158 (40%-100%) Colours:

Black

SPCK specification: ZMS_CAR_153x40x78

Design:

octapharma® Satzstudio Borngräber



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Powder and solvent for solution for infusion Human Prothrombin Complex, freeze-dried

Equipment pack for reconstitution and infusion.

This package contains:

- 1 Double-ended needle
- 1 Filter needle
- 1 Disposable syringe
- 1 Infusion set
- 2 Alcohol swabs 1 Vial with 20 ml Water for Injections Ph. Eur.

Do not store above 25°C. Do not freeze. See Package Insert for instructions for use. Keep out of the reach of children. Jauhi dari kanak-kanak.

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Product Registration Holder: Pharmaniaga Marketing Sdn Bhd (198401005734) No 7, Lorong Keluli 1B, Kaw. Perindustrian Bukit Raja Selatan Seksyen 7, 40000 Shah Alam

Selangor Darul Ehsan Malaysia Manufactured by: OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.

A-1100 Vienna, Austria octapharma®

Oberlaaer Strasse 235

octaplex®

Powder and solvent for solution for infusion **Human Prothrombin Complex, freeze-dried**

Equipment pack for reconstitution and infusion.

This package contains:

- 1 Double-ended needle
- 1 Filter needle
- 1 Disposable syringe
- 1 Infusion set
- 2 Alcohol swabs
- 1 Vial with 20 ml Water for Injections Ph. Eur.

Do not store above 25°C. Do not freeze. See Package Insert for instructions for use. Keep out of the reach of children. Jauhi dari kanak-kanak.

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Product Registration Holder: Pharmaniaga Marketing Sdn Bhd

(198401005734) No 7, Lorong Keluli 1B, Kaw. Perindustrian Bukit Raja Selatan Seksyen 7, 40000 Shah Alam Selangor Darul Ehsan Malaysia

Manufactured by: OCTAPHARMA Pharmazeutika Produktionsges.m.b.H. Oberlaaer Strasse 235 A-1100 Vienna, Austria

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