

Solifenacin-Trima 5mg & 10mg Tablets**Solifenacin Succinate 5mg & 10 mg**

<u>Manufacturer:</u>	Trima Israel Pharmaceutical Products Maabarot Ltd.
<u>Dossier status:</u>	Complete CTD file
<u>Dossier date:</u>	Dossier is ready, submitted to Israeli MOH 12/2012 and approved July 2014.
<u>Dosage form:</u>	Tablets

Bioequivalence reference:

The reference product is **VESICARE** (Solifenacin Succinate) 10mg tablets, manufactured by Astella Pharma Europe B.V Netherlands, Sourced in Israel.

<u>Stability data:</u>	3 batches, 3 months at 40°C, 75% RH 3 batches, 3 years at 25°C, 60% RH
<u>Packaging:</u>	Tablets are packed in Aluminum foil blister packs

The European Union (EU) has in place an agreement (2013/1/EU) on conformity assessment and mutual acceptance of Pharmaceutical Good Manufacturing Practice (GMP) with Israel. The Trima manufacturing facility is therefore considered as EU-GMP compliant.

For further information, please contact:

Products protected by patents in force are neither offered for sale nor marketed in jurisdictions where such activities would constitute patent infringement.

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