

**Rasagiline-Trima Tablets****Rasagiline (as Mesylate) 1 mg**

<u>Manufacturer:</u>	<b>Trima Israel Pharmaceutical Products Maabarot Ltd.</b>
<u>Dossier status:</u>	Complete CTD file
<u>Dossier date:</u>	Dossier ready, submitted to Israeli MOH in 07/2015 and approved March 2016.
<u>Dosage form:</u>	Tablets

Bioequivalence reference:

The reference product is **AZILECT** (Rasagiline as mesylate) 1mg tablets, manufactured by TEVA Pharmaceutical Industries Ltd, Source country: Israel.

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

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