

**Tinden Drops**Active ingredient : **Dimetindene Maleate** 1mg/1ml(Equivalent to Fenistil, Novartis <sup>TM</sup>)

<b>Manufacturer</b>	Trima Israel Pharmaceutical Products Ltd.
<b>Dossier Type</b>	CTD
<b>Dossier Status</b>	Dossier ready, submitted to Israeli MOH in <b>November 2016</b> and approved in <b>July 2018</b>
<b>Dosage form</b>	Oral drops
<b>Bioequivalence reference</b>	Not applicable (a true solution ).
<b>Stability data</b>	<p>Pilot batches were packed in Alu/Alu blister packs and incubated under the following conditions:</p> <p>40°C/75%RH for 6 months</p> <p>30°C/65%RH for up to 12 months</p> <p>25°C/60%RH for up to 18 months</p> <p>According to the finished dosage manufacturing procedures, the first three commercial batches will go into long term stability study. After that, an additional one batch a year will join the long term stability study.</p>
<b>Packaging:</b>	Bottle glass, 20ml.

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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