

Thank you for your recent enquiry regarding Eltroxin (levothyroxine).

I understand you would like information on crushing the tablet.

### **Israeli Summary of Product Characteristics (1)**

As you may know the SPC includes the following relevant information.

#### **CLINICAL INFORMATION**

##### **Dosage and Administration**

Due to a lack of data it is not appropriate to crush thyroxine tablets and thyroxine tablets without a score-line must not be halved. Thyroxine tablets should preferably be taken on an empty stomach.

##### **Warnings and Precautions**

Thyroxine has a narrow therapeutic index. Appropriate thyroxine dosage is based upon clinical assessment and laboratory monitoring of thyroid function tests. During the initial titration period, careful dosage titration and monitoring is necessary to avoid the consequences of under- or over-treatment. The symptoms of excessive thyroxine dosage are the same as many features of endogenous thyrotoxicosis.

##### **Pharmacokinetics**

###### **Absorption**

Following oral administration the absorption of thyroxine is incomplete and variable especially when taken with food. The amount absorbed increases during fasting conditions.

##### **Patient Information Leaflet (2)**

Do not chew. Swallow the medicine with a small amount of water. Do not crush or halve the tablet. It is recommended to take this medicine on an empty stomach.

#### **Chemical Stability and Bioequivalence**

There is no specific stability data on crushed tablets, however during analytical testing / dissolution testing tablets dissolved in aqueous solutions. For that reason it is demonstrated that crushed tablets which are immediately put into water and used directly after the preparation of such mixtures are chemically stable for a while. ( e.g. 45 min at room temperature ). Therefore we have data to support only the chemical stability of crushed Eltroxin tablets in water directly before use. Care must also be taken that the all intended dose is taken.

#### **Clinical Discretion**

Bearing all the above in mind, it is important to note that although it is not Aspen's recommendation that the tablets be crushed, it is recognised there may be occasions where this practice may be used, any deviation from the product labelling is at the clinical discretion of the treating healthcare professional. The decision to treat administer the tablet outside of the product label must be weighed against the risk of no treatment or the patient not receiving the complete dose.

As you may appreciate one of the most important aspects in the treatment of hypothyroidism is consistency in medication administration and regularity in the performance of thyroid function tests, followed by the appropriate dose adjustment.

I hope this information is of value.

Please do not hesitate to ask if we may be of further assistance.

Yours sincerely,

Medical Information Service

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Israeli Medical Information Helpline: 1809 212 832 (freephone) or +44 1748 828 379



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#### References

1. Israeli Eltroxin, Summary of Product Characteristics, Perrigo on behalf of Aspen (Aug 2010)
2. Israeli Eltroxin, Patient Information Leaflet, Perrigo on behalf of Aspen (Mar 2010)