

## **SB TITCK 03.04.2024 ORNIDAZOL İÇEREN İLAÇLAR- ACIL GÜVENLİLİK KISITLAMASI\_EN**

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency

Number: E-24931227-510.01.04-1440410 03.04.2024 Subject: Ornidazole-containing products – Urgent Safety Restriction

### **FILE**

The Agency has given consideration to the cases of liver failure requiring liver transplantation with products containing ornidazole that have been reported to TÜFAM. Accordingly, the wording provided in the attachment must be incorporated in the local Summary of Product Characteristics (KÜB) and Package Leaflet (KT) of said products. KÜBs for reference products incorporating the requisite changes must be submitted to the Pharmacologic Assessment Unit for review within 15 days of this announcement. Submissions for other products containing ornidazole must be made to the Pharmacologic Assessment Unit within 15 days after the KÜB for the reference product has been posted on the Agency's official website. For products which contain this active substance but which has no reference or no actively marketed reference, submissions must be made to the Pharmacologic Assessment Unit within 15 days after this announcement, without waiting for posting of a KÜB/KT on the Agency's official website for any reference product. For your information and appropriate action.

Dr. Asım Hocaoglu Agency President

Distribution: Turkish Pharmaceutical Manufacturers Association Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Türkiye Health Products Association

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Turkish Ministry of Health Turkish Medicines and Medical Devices Agency  
LOCAL SUMMARY OF PRODUCT CHARACTERISTICS [...]

#### **4.4 Special warnings and precautions for use**

Cases of acute liver failure and, in some cases, severe toxic hepatitis requiring liver transplantation have been reported in Türkiye in patients receiving ornidazole alone or in combination with other drugs. Close monitoring of hepatic enzymes is recommended during treatment.

[...]

#### **4.8 Undesirable effects**

Hepatobiliary disorders Not known: Pancreatitis, jaundice, hepatocellular liver injury, cholestatic or mixed-type hepatitis and elevated liver enzymes (AST, ALT, ALP, GGT) which may be reversible by stopping treatment have been reported. Cases of acute liver failure and, in some cases, severe toxic hepatitis requiring liver transplantation have been reported in patients receiving ornidazole alone or in combination with other drugs. Close monitoring of hepatic enzymes is recommended during treatment.(see Section 4.4).

LOCAL PACKAGE LEAFLET [...]

## **2. What you need to know before taking <product name>**

EXERCISE CAUTION when using <product name> in the following cases:

Cases of acute liver failure and, in some cases, severe toxic hepatitis requiring liver transplantation have been reported in Türkiye in patients receiving ornidazole alone or in combination with other drugs. Close monitoring of hepatic enzymes is recommended during treatment.

[...]

#### 4. Possible side effects

Frequency not known: • Pancreatitis, jaundice, hepatocellular liver injury, cholestatic or mixed-type hepatitis and elevated liver enzymes (AST, ALT, ALP, GGT) which may be reversible by stopping treatment have been reported. • Cases of acute liver failure and, in some cases, severe toxic hepatitis requiring liver transplantation have been reported in patients receiving ornidazole alone or in combination with other drugs.

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