

09.06.2021 HEPATIT B İMMÜNOGLOBULIN İÇEREN ÜRÜNLER HK_ENG

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey

Number : E-62820468-000-429089 Subject : Products Containing Hepatitis B Immunoglobulin NORMAL

06.05.2021 DOSSIER

Ref: Our association announcement dated 04.11.2016, with No. 77893119-000-143546

In line with the decision adopted by the “Clinical Evaluation Commission of Medicinal Products for Human Use” of our Agency regarding the products containing Hepatitis B immunoglobulin, the referred letter has been revoked and it is necessary for the preparations containing the referred active substance should be arranged as follows.

Hepatitis B Immunoglobulin may be administered for prophylactic purposes in the following circumstances where there is acute development of Hepatitis B or a high risk of such development.

1- Under the following conditions in case of risk of being infected with blood or bodily secretions containing or with a high risk of containing HBsAg, in newborn babies of HBsAg-positive mothers and in case of domestic contact with a person who is infected with acute Hepatitis B, a- Risky encounter with blood containing HBsAg, direct contact in the parenteral (needle stick injury, bite, deep wound) or mucosal surfaces (accidental spilling to the eye-oral mucosa), oral ingestion (accidental drinking-pipetting) or encounter or intake of blood, serum or plasma, b- Where a baby (regardless of being HBsAg-positive or negative) is born (via regular or C-section delivery) from a HBsAg-positive mother perinatally, c- Suspicious intercourse with HBsAg-positive sexual partner, d- In the presence of someone at home who had acute Hepatitis B infection, not previously immunized infants younger than 12 months and infants older than 12 months who had a risky contact with their blood. The relevant person should not have been previously received Hepatitis B vaccine for such administrations. 2- Vaccine response should also be taken into account in the assessment of healthcare professionals following a risky contact. Individuals in whom no antibody response was achieved despite being vaccinated should be regarded as unvaccinated. 3- In liver transplant recipients with risk of recurrence after liver transplantation.

I hereby submit for your information and kindly request for the conduct of relevant action for the submission of any remarks, proposals and remarks regarding the decision adopted within 10 (ten) days as of the date of publication of this association announcement, and that no application is made to the Pharmacological Evaluation Unit and Registration Unit regarding “Products Containing Hepatitis B Immunoglobulin” during the referred process.

Spec. Pharm. Oğuzhan KOYUNCU on behalf of the President of the Agency Head of Department

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association Turkish Foundation on Pharmaceuticals, Pharmacy, Health Sciences and Technologies

RESTRICTED Revoked.

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey

No. : 7789311-000-143546 Subject: Products containing HEPATITIS B immunoglobulin 04.11.2016 DOSSIER

In line with the decision adopted by the “Clinical Evaluation Commission on Medicinal Products for Human Use” of our Agency regarding products containing HEPATITIS B immunoglobulin, the indications of the preparations containing the referred active substance should be arranged as follows.

Hepatitis B Immunoglobulin may be used under the following conditions for prophylactic purposes in case of an acute encounter with Hepatitis B or high risk of such an encounter.

1- In the following cases of risk-generating encounter with blood or bodily secretions containing or with high risk of containing HBsAg, or domestic contact with babies born from an HBsAg- positive mother or a person infected with acute Hepatitis B, a- Risky encounter with blood containing HBsAg, direct contact in the parenteral (needle stick injury, bite, deep wound) or mucosal surfaces (accidental spilling to the eye-oral mucosa), oral ingestion (accidental drinking-pipetting) or encounter or intake of blood, serum or plasma, b- Where a baby (regardless of being HBsAg-positive or negative) is born (via regular or C- section delivery) from a HBsAg-positive mother perinatally, c- Presence of a HBsAg-positive sexual partner, d- In the domestic presence of someone infected with acute Hepatitis B, not previously immunized infants younger than 12 months and infants older than 12 months who had a risky contact via blood. In such administrations, the relevant person should not have been received Hepatitis B vaccine previously. 2- Vaccine response should also be taken into account in the assessment of healthcare professionals following a risky contact. Individuals in whom no antibody response was achieved despite being vaccinated should be regarded as unvaccinated. 3- In liver transplant recipients with risk of recurrence after liver transplantation.

I hereby submit for your information and kindly request for the conduct of relevant action on the need to provide relevant information to the member companies of your Association on this topic and apply to the "Pharmacological Evaluation Unit" along with SPCs-PL samples in which the requirements relating to the topic mentioned above have been fulfilled latest by 22.11.2016.

Dr. Hakkı GÜRSÖZ President of the Agency Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Association of Innovator Pharmaceutical Companies Self-Care Products Association Turkish Pharmaceutical Industry Association