

15.10.2020 TARİHLİ D VİTAMİNİ İÇEREN İLAÇLAR HK_ENG

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

12.10.2020

DOSSIER

Ref: Our Association announcement dated 11.10.2019, with No. 159357

The referred announcements regarding the medicines containing vitamin D alone has been revoked and it is necessary to arrange as follows the sections on indication, posology, warnings and precautions in the Summary of Product Characteristics (SPC) and Package Leaflet (PL) of the referred products.

For parenteral products containing vitamin D: The term “oral” cannot be used in the product name and SPC-PL information. Indications: It should be edited as: “It is indicated only for patients with gastrointestinal malabsorption in vitamin D deficiency”. For Orally Administered Products Containing Vitamin D: Indications: It should be edited as “It is indicated for treatment, maintenance treatment and prophylaxis of vitamin D deficiency”. For Products Administered Orally (in Liquid-Solid Form) and Parenterally: Posology and mode of administration: It should be edited as: “Your doctor will decide on how to use the medicine. Use as advised by your doctor.”

Age Group Recommended Prophylactic / Maintenance Dose Therapeutic Dose for Vitamin D Deficiency Highest Tolerable Dose for Maintenance Therapy and Prophylaxis of High-Risk Groups (To be specified in the warnings section) Daily treatment ** Weekly administration Newborn 400 IU/day (10 µg/day) 1000 IU/day (25 µg/day) NA 1000 IU/day (25 µg/day) 1 month-1 year 400 IU/day (10 µg/day) 2000-3000 IU/day (50-75 µg/day) NA 1500 IU/day (37.5 µg/day) No. : 62820468-000-E.23080 Subject : Medicines containing vitamin D

1-10 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 2000 IU/day (50 µg/day)

11-18 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 4000 IU/day (100 µg/day) Adults above 18 years 600-1500 IU/day (15-37.5 µg/day) 7000-10.000 IU/day (175- 250 µg/day) 50.000 IU/week (1250 µg/week)*** 4000 IU/day (100 µg/day) * The dose may be increased up to 1000 IU where necessary. ** It may be used for up to 6-8 weeks. *** In case it is preferred to use the weekly dose instead of the daily dose, 50,000 IU may be used once as a single weekly dose for up to 6-8 weeks.

Special Warnings and Precautions for Use In case of use during pregnancy, the relevant sections of the SPCs and PLs should be edited in line with the following information: a) Although routine use of medicines containing vitamin D is not recommended during pregnancy, where necessary, they should be used under the supervision of a doctor. b) Prophylactic use of medicines containing vitamin D during pregnancy should not exceed a maximum dose of 1000 IU/day.

The deadline for submission of objections relating to abovementioned changes in registered products containing Vitamin D alone is expired and it is necessary to present the SPC/PL applications comprising the changes made in the announcement to the Pharmacological Evaluation Unit within 1 month as of the date of publication of this announcement for review, to present the applications relating to products with ongoing registration process to the Registration Unit and to take into account this announcement also for products for which registration application will be made. The referred application should not be submitted to the Clinical Evaluation Unit. I hereby submit for your information for the conduct of relevant action.

Assoc. Prof Dr. Tolga KARAKAN Deputy President of the Agency

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

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

17.09.2019

DOSSIER

Ref: Our Association announcement dated 11.10.2019, with No. E.159357

The referred announcement regarding the medicines containing vitamin D alone has been revoked and it is necessary to arrange as follows the sections on indication, posology, warnings and precautions in the Summary of Product Characteristics (SPC) and Package Leaflet (PL) of the referred products.

For parenteral products containing vitamin D: The term "oral" cannot be used in the product name and SPC-PL information.

Indications: It should be edited as: "It is indicated only for patients with gastrointestinal malabsorption in vitamin D deficiency".

For Orally Administered Products Containing Vitamin D: Indications: It should be edited as "It is indicated for the treatment, maintenance and prophylaxis of vitamin D deficiency." For Products Administered Orally (in Liquid-Solid Form) and Parenterally: Posology and mode of administration: It should be edited as: "Your doctor will decide on how to use the medicine. Use as advised by your doctor."

Age Group Recommended Prophylactic /Maintenance Dose Therapeutic Dose for Vitamin D Deficiency Highest Tolerable Dose for Maintenance Therapy and Prophylaxis of High-Risk Groups (To be specified in the warnings section) Daily treatment ** Weekly administration No. : 62820468-000-E.210253 Subject : Medicines containing vitamin D

Newborn 400 IU/day (10 µg/day) 1000 IU/day (25 µg/day) NA 1000 IU/day (25 µg/day) 1 month-1 year 400 IU/day (10 µg/day) 2000-3000 IU/day (50-75 µg/day) NA 1500 IU/day (37.5 µg/day) 1-10 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 2000 IU/day (50 µg/day) 11-18 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 4000 IU/day (100 µg/day) Adults above 18 years 600-1500 IU/day (15-37.5 µg/day) 7000-10.000 IU/day (175- 250 µg/day) 50.000 IU/week (1250 µg/week)*** 4000 IU/day (100 µg/day) * The dose may be increased to 1000 IU where necessary. ** It may be used for up to 6-8 weeks. *** In case it is preferred to use the weekly dose instead of the daily dose, 50,000 IU may be used once as a single weekly dose for up to 6-8 weeks. It is not advised to use of more than 50,000 IU of vitamin D at once.

Special Warnings and Precautions for Use: In case of use during pregnancy, the relevant sections of the SPCs and PL should be edited in line with the following information: c) Although routine use of medicines containing vitamin D is not recommended during pregnancy, where necessary, they should be used under the supervision of a doctor. d) Prophylactic use of medicines containing vitamin D during pregnancy should not exceed a maximum dose of 1000 IU/day.

I hereby submit for your information and kindly request that objections to this decision, if any, are submitted to the Clinical Evaluation Unit within 5 workdays and that no SPC/PL application for vitamin D is made to the Clinical Evaluation Unit and Pharmacological Evaluation Unit during this period.

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

RESTRICTED Revoked

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

11.10.2019

DOSSIER

Ref: a) Our Association announcement dated 18.03.2019, with No. E.46137 b) Our Association announcement dated 27.03.2019, with No. E.51756 The announcements indicated in (a) and (b) regarding the medicines containing vitamin D alone have been revoked and it is necessary to arrange as follows the sections on indication, posology, warnings and precautions in the Summary of Product Characteristics (SPC) and Package Leaflet (PL) of the referred products.

For parenteral products containing vitamin D: The term "oral" cannot be used in the product name and SPC-PIL information.

For Products Administered Parenterally containing more than 50,000 IU of Vitamin D: Indications: It should be edited as: "It is indicated only for patients with gastrointestinal malabsorption in vitamin D deficiency".

Posology: The statement reading, "Your doctor will decide on how to use the medicine. Use as advised by your doctor." should be written before the table "Posology and mode of administration" under the title "For Orally (in Liquid-Solid Form) and Parenterally Administered Products".

For Orally Administered Products Containing 50,000 IU of Vitamin D: Indications: It should be edited as "It is indicated only for patients with intestinal fat malabsorption in vitamin D deficiency".

Posology: The statement reading, "Your doctor will decide on how to use the medicine. Use as advised by your doctor." should be written before the table "Posology and mode of administration" under the title "For Orally (in Liquid-Solid Form) and Parenterally Administered Products".

For Products Containing 50,000 IU and less of vitamin D: Indications: "It is indicated for the treatment, maintenance and prophylaxis of vitamin D deficiency."

No. : 62820468-000-E.159357 Subject : Medicines containing vitamin D

For Products Administered Orally (in Liquid-Solid Form) and Parenterally: Posology and mode of administration:

Age Group Recommended Prophylactic / Maintenance Dose Therapeutic Dose for Vitamin D Deficiency Highest Tolerable Dose for Maintenance Therapy and Prophylaxis of High-Risk Groups (To be specified in the warnings section) Daily treatment ** Weekly administration Newborn 400 IU/day (10 µg/day) 1000 IU/day (25 µg/day) NA 1000 IU/day (25 µg/day) 1 month-1 year 400 IU/day (10 µg/day) 2000-3000 IU/day (50-75 µg/day) NA 1500 IU/day (37.5 µg/day) 1-10 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 2000 IU/day (50 µg/day)

11-18 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 4000 IU/day (100 µg/day) Adults above 18 years 600-1500 IU/day (15-37.5 µg/day) 7000-10.000 IU/day (175- 250 µg/day) 50.000 IU/week (1250 µg/week)*** 4000 IU/day (100 µg/day) * The dose may be increased to 1000 IU where necessary. ** It may be used for up to 6-8 weeks. *** In case it is preferred to use the weekly dose instead of the daily dose, 50,000 IU may be used once as a single weekly dose for up to 6-8 weeks.

Special Warnings and Precautions for Use In case of use during pregnancy, the relevant sections of the SPCs and PLs should be edited in line with the following information: a) Although routine use of medicines containing vitamin D is not recommended during pregnancy, where necessary, they should be used under the supervision of a doctor.

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b) Prophylactic use of medicines containing vitamin D during pregnancy should not exceed a maximum dose of 1000 IU/day.

I hereby submit for your information and kindly request that the SPC/PL applications relating to the products in which abovementioned changes are made are sent to the Clinical Evaluation Unit within 10 workdays for review.

Spec. Pharm. Hacer COŞKUN ÇETİNTAŞ 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

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Revoked

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

NORMAL 18.03.2019

DOSSIER

The indication, posology, warnings and precautions sections in the Summary of Product Characteristics (SPC) and Package Leaflet (PL) of the medicines containing vitamin D alone should be edited as indicated below: Indications: The indications of the preparations containing more than 50,000 IU of vitamin D, to be used parenterally, should be edited as: "It is indicated only for patients with gastrointestinal malabsorption in vitamin D deficiency". Posology and mode of administration:

Age Group Recommended Prophylactic / Maintenance Dose Therapeutic Dose for Vitamin D Deficiency Highest Tolerable Dose for Maintenance Therapy and Prophylaxis of High-Risk Groups (To be specified in the warnings section) Daily treatment ** Weekly administration Newborn 400 IU/day (10 µg/day) 1000 IU/day (25 µg/day) NA 1000 IU/day (25 µg/day) 1 month-1 year 400 IU/day (10 µg/day) 2000-3000 IU/day (50-75 µg/day) NA 1500 IU/day (37.5 µg/day) 1-10 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 2000 IU/day (50 µg/day) Number : 62820468-000-E.46137 Subject : Medicines containing vitamin D

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11-18 years 400-800* IU/day (10-20 µg/day) 3000-5000 IU/day (75-125 µg/day) NA 4000 IU/day (100 µg/day) Adults above 18 years 600-1500 IU/day (15-37.5 µg/day) 7000-10.000 IU/day (175- 250 µg/day) 50.000 IU/week (1250 µg/week)*** 4000 IU/day (100 µg/day) * The dose may be increased to 1000 IU where necessary. ** It may be used for up to 6-8 weeks. *** In case it is preferred to use the weekly dose instead of the daily dose, 50,000 IU may be used once as a single weekly dose for up to 6-8 weeks. Note: The sections related with the posology of the preparations containing more than 50,000 IU of vitamin D and to be used parenterally should be edited as "Your doctor will decide on how you should use your medicine. Take it as advised by your doctor."

Special Warnings and Precautions for Use (In case of use during pregnancy, the relevant sections of the SPCs and PLs should be edited in line with the following information.): a) Although routine use of medicines containing vitamin D is not recommended during pregnancy, where necessary, they should be used under the supervision of a doctor. b) Prophylactic use of medicines containing vitamin D during pregnancy should not exceed a maximum dose of 1000 IU/day.

I hereby submit for your information and kindly request that the SPCs/PLs in which abovementioned changes are made are sent to the Pharmacological Evaluation Unit until 12.04.2019 for review.

Dr. Pharm. Harun KIZILAY Deputy President of the Agency

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RESTRICTED Revoked

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

27.03.2019

DOSSIER

Ref: Our Association announcement on “Medicines containing vitamin D”, dated 18.03.2019, with No. E.46137. It is necessary to remove the term “oral” from the product name and Summary of Product Characteristics and Package Leaflet of the products containing 300.000 I.U. / mL vitamin D and including the term “oral” in the product name and to submit an application in line with our Association announcement.

I hereby submit for your information and kindly request that the SPC/PL applications relating to the products in which abovementioned changes are made are sent to the Clinical Evaluation Unit until 19.04.2019 for review.

Dr. Hakkı GÜRSÖZ President of the Agency

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 No. : 62820468-000-E.51756
Subject : Medicines containing vitamin D