YODOCEFOL 200/400/2 micrograms tablets (IODINE, FOLIC ACID, VITAMIN B12 )
1. WHAT IS YODOCEFOL AND WHAT IS IT USED FOR? YODOCEFOL is indicated for the prevention of iodine, folic acid and vitamin B12 deficiency disorders in pregnant woman during the first quarter of pregnancy and during one month before conception, for the prophylaxis of abnormal development of the central nervous system of the fetus (neural tube defect and neurological disorders).
2. WHAT YOU NEED TO KNOW BEFORE TAKING YODOCEFOL? Do not take YODOCEFOL in case of: Allergy (hypersensitivity) to potassium iodide, folic acid, vitamin B12 or any of YODOCEFOL excipients Especially related to potassium iodide. Acute bronchitis. Overt hyperthyroidism (over activity of the thyroid gland with symptoms). Latent hyperthyroidism (over activity of the thyroid gland without symptoms). Your daily dosage should not exceed 150 micrograms of iodine. Take special care with YODOCEFOL: Treatment with YODOCFOL to epileptic patients should be administered under strict medical control. This drug contains potassium iodide. Since some people are particularly sensitive to iodine, special care should be taken before starting the treatment. Iodides may affect the thyroid gland. Administration of iodides may affect thyroid function tests. Do not use iodate disinfectants on newborns or pregnant women. Always inform your doctor before taking this drug in case of: Hypocomplementemic vasculitis (vessel inflammation), goitre (increase of the volume of thyroid gland) or autoimmune thyroiditis (increase of the volume of thyroid gland) are at risk of side effects consequent to iodine administration. Special care should be taken when starting the treatment in patients with renal diseases, hyperkalaemia (concentration of the potassium in the blood is elevated), goiter or active tuberculosis. Intake of other drugs: Tell your doctor or pharmacist if you are or were taking other drugs, including those without prescription. Some drugs may interact with YODOCEFOL. In this case it may be necessary to adjust the dosage, suspend either treatment or wait at least three hours between administrations of the different drugs. It is important that you inform your doctor if you are taking or have recently taken any of the following drugs: Antiulcer drugs (drugs used to treat gastric acidity). Chloramphenicol (antibiotic). Phenytoin (anticonvulsant drug). Folic acid antagonist (Methotrexate). Fluorouracil (drug for cancer). Potassium-sparing diuretics. Lithium salts. Antithyroid drugs (for the treatment of hyperthyroidism). Other possible interactions: antiepileptics, oestrogens, prolonged use of corticosteroids, association of trimethoprim/ sulfametoxazole (for the treatment of some infections) and alcohol abuses. Interactions with diagnostic tests: Iodides may affect the thyroid gland. Administration of iodides may affect thyroid function tests. Refer to your doctor if you need to take a blood or urine test. Taking YODOCEFOL with food and drinks: There are no known interactions of YODOCEFOL with any food or drink. Pregnancy and lactation: YODOCEFOL is indicated for the prevention of iodine, folic acid and vitamin B12 deficiencies before and during pregnancy, because it contains those three active ingredients at doses recommended for pregnancy. Potassium iodide, folic acid and vitamin B12 at doses exceeding those daily recommended should be administered to pregnant women under strict medical control and upon assessment of the risk-benefit ratio.Seek your doctor's or pharmacist's advice before taking any drug. Effects of ability to drive and use machines: No effects on the ability to drive and use machines were observed. Important information on some ingredients of YODOCEFOL: This drug contains lactose. If you were diagnosed with intolerance to some sugars, ask your doctor before taking this drug. 3. HOW TO TAKE YODOCEFOL? Carefully follow the administration instructions for YODOCEFOL given by your doctor. If you have any doubts, ask your doctor or pharmacist. The regular dosage is one tablet daily, preferably before meals. If you take a greater YODOCEFOL dose than recommended: In case of accidental overdose or ingestion, immediately report to your doctor or pharmacist or call Toxicology Information Service. Intentional or accidental intoxication is highly unlikely. Much higher doses than recommended or for longer periods may cause metallic taste, burning in the mouth and throat, soreness of teeth and gum, increased salivation, running nose, sneezing and eye irritation with eyelid swelling (symptom known as « iodism »). Strong headache, cough, pulmonary oedema (pulmonary fluid accumulation), as well as swelling and sensitization of parotid and submaxillary glands (glands located under the lower jaw) may also occur. Inflammation of the pharynx, the larynx and amygdala may also occur. Moderate eruptions may develop on seborrhoeic areas. Severe eruptions are uncommon. Gastric irritation is common with extremely high doses and diarrhea-sometimes bloody diarrhea- may occur. Signs and symptoms of iodism usually subside spontaneously within a few days of treatment suspension. Large doses of potassium iodide over long periods of time may cause thyroid gland hyperplasia (enlargement), goiter and severe hypothyroidism. If you miss a dose of YODOCEFOL: Do not take a double dose to make up for the missed one, but simply take the missed dose whenever you realize and take the next dose at regularly scheduled interval (24 hours). If you suspend treatment with YODOCEFOL: Your doctor will advise you on the treatment's duration. Do not suspend treatment earlier, even if you feel better, or it will not have the expected efficacy. If you have any doubts on the use of this drug, ask your doctor or pharmacist. 4. WHAT ARE THE POSSIBLE ADVERSE EVENTS? Like any other drug, YODOCEFOL may cause adverse events, though not all patients would be affected. The following adverse reactions were observed, classified by organs and systems and by frequency. Frequency was ranked uncommon (≥ 1/1000 ; < 1/100). Blood and lymphatic system disorder: Thrombotic thrombocytopenic purpura (blood disorder characterized by low number of circulating platelets and red blood cells). Endocrine disorders: Goiter . Hyper and hypothyroidism (Abnormal thyroid function). Gastrointestinal disorders: Transient diarrhea, nauseas, vomiting, abdominal pain/distension, flatulence metallic taste and increased salivation.Disorders of the skin and subcutaneous tissue: Itching, skin eruptions, erythema (inflammatory reddening of the skin), urticaria, (eruption in the form of itchy bumps) and angioedema (development of large bumps, especially around the eyes, lips, and throat). Vascular disorders: Vasculitis (hypersensitivity to treatment leading to skin vessel inflammation and damage). Fatal periarteritis (vascular disease in which small and medium-sized arteries get inflamed and damaged. Immune system disorders: Oedema including facial oedema and oedema of glottis. General disorders: Hypersensitivity and general malaise. Refer to your doctor or pharmacist if you experience any severe adverse events on any adverse event not mentioned in this leaflet. 5. HOW TO STORE YODOCEFOL? No special precautions for storage are required. Keep out of the reach and sight of children. Shelf life: Do not use YODOCEFOL after the expiry date printed on the container. Expiry date is the last date of the month indicated. Drug should not be disposed of in drains or in the rubbish. To help preserve the environment, ask your pharmacist for best disposal of containers and unnecessary drugs. 6. ADDITIONAL INFORMATION: Composition of YODOCEFOL.The active ingredients include iodine, folic acid and vitamin B12(cyanocobalamin). Each tablet contains 262 micrograms of potassium iodide (equivalent to 200 micrograms of elemental iodine), 400 micrograms of folic acid and 2 micrograms of vitamin B12. The other components are: lactose monohydrate 110 mesh, microcrystalline cellulose, sodium starch glycolate from potato, Calcium Stearate, trisodium citrate, citric acid and maltodextrins. Product appearance and contents of container: YODOCEFOL appears as round, yellow tablets for oral administration in blisters. Total of 28 tablets. Tablets are arranged in sequence following the days of the week, in order to facilitate administration. Marketing Authorisation Holder: ITALFARMACO, S.A. C/ San Rafael, 3 - 28108 Alcobendas (Madrid) - Spain. Distributed by: VERSALYA PHARMA S.L. - ITALFARMACO Group C/ San Rafael, 3 - 28108 Alcobendas (Madrid) - Spain