Prescribing Information

*pHis0Hex®*  
(hexachlorophene)

Bottles of 150 mL, 450 mL

Pharmaceutical standard: USP

Antibacterial – Skin Cleanser

sanofi-aventis Canada, Inc.  
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**pHisoHex®**

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**Description:** pHisoHex is an antibacterial sudsing emulsion. It contains entsufon (sodium octylphenoxyethoxyethyl ether sulfonate), lanolin cholesterols, petrolatum and 3% hexachlorophene on a total weight basis. It is a colloidal dispersion of the active ingredients in a stable emulsion. Entsufon is a synthetic detergent which is effective in many kinds of water hard or soft, cold or hot and under acid as well as alkaline conditions.

**Indications:** A general antibacterial cleansing agent with bacteriostatic activity against staphylococci and other gram-positive bacteria. It is indicated for use as a surgical scrub and for thorough washing and cleansing of the skin, to reduce bacterial colonization and to prevent the spread of infection.

**Contraindications:** Do not use on burned or denuded skin; as an occlusive dressing, wet pack or lotion; as vaginal pack or tampon, on mucous membranes or for routine prophylactic total body bathing.

Should not be used on persons hypersensitive to any of its components nor on persons who have demonstrated primary light sensitivity to halogenated phenol derivatives because of the possibility of cross-sensitivity to hexachlorophene.

**Precautions:** Rinse thoroughly after use especially from sensitive areas such as the scrotum and perineum. Patients should be closely monitored and use should be immediately discontinued at the first sign of any of the symptoms described below.

Rapid absorption of hexachlorophene may occur with resultant toxic blood levels when preparations containing hexachlorophene are applied to skin lesions such as ichthyosis congenita, the dermatitis of Letterer-Siwe's syndrome, or other generalized dermatological conditions. Application to burns has also produced neurotoxicity and death. Detectable blood levels of hexachlorophene following absorption through intact skin have been found in subjects who regularly scrubbed with hexachlorophene 3%.

**Hexachlorophene should be discontinued promptly if signs or symptoms of cerebral irritability occur.**

Children: Infants, especially premature infants or those with dermatoses, are particularly susceptible to hexachlorophene absorption. Systemic toxicity may be manifested by signs of CNS stimulation (irritation) sometimes with convulsions.
Infants have developed dermatitis, irritability, generalized clonic muscular contractions and decerebrate rigidity following application of 6% hexachlorophene powder. Examinations of brain stems of these cases revealed vacuolization like that which can be produced in newborn experimental animals following repeated topical application of 3% hexachlorophene. Moreover, a histological study has shown a positive correlation between hexachlorophene baths and brain tissue lesions in premature infants who died of unrelated causes.

Intended for external use only. If swallowed, it is especially harmful to infants and children. Do not pour into measuring cups, medicine bottles, or similar containers since it may be mistaken for baby formula or other medication.

Suds that get into the eyes accidentally during washing should be rinsed out promptly and thoroughly with water.

Periorbital skin and head application should be performed while the patient is conscious, so that eye irritation can be reported immediately.

Topical exposure of neonatal rats to 3% hexachlorophene solution caused reduced fertility in 7-month-old males, due to inability to ejaculate.

**Pregnancy:** Hexachlorophene is embryo toxic and produces some teratogenic effects in rats. There are no adequate studies in pregnant women. Hexachlorophene should be used during pregnancy only if the potential benefits justify potential risk to the fetus.

Hexachlorophene has been shown to be teratogenic and embryotoxic in rats when given by mouth or instilled into the vagina in large doses. Administration of 500 mg/kg diet or 20 to 30 mg/kg body weight/day by gavage to rats caused some malformations (angulated ribs, cleft palate, micro- and anophthalmia) and reduction in litter size. Placental transfer and excretion in milk of hexachlorophene has been demonstrated in rats. In another study, doses of up to 50 mg/kg diet failed to produce any effects in 3 generations of rats. Hexachlorophene did not interfere with reproduction in hamsters.

**Lactation:** Placental transfer and excretion in milk of hexachlorophene has been demonstrated in rats. It is not known whether this drug is excreted in human milk. Because of the potential risk to newborn infants, a decision is required to discontinue nursing or to discontinue the drug.

Children: pHisoHex should not be used routinely for bathing infants (see Precautions). For premature infants, see Precautions.

**Adverse Effects:** Adverse reactions may include dermatitis and photosensitivity. Hexachlorophene is not irritating to the skin in ordinary concentrations and hypersensitivity reactions are rare. Primary light sensitivity occurs rarely but patients who
have developed photo-allergy to other halogenated phenol derivatives may sometimes exhibit cross-sensitivity to hexachlorophene. If a sensitivity reaction occurs, discontinue use of the product and consult a physician.

Sensitive skin may react with redness and/or mild scaling or dryness, especially when exposed to excessive rubbing, heat or cold.

Use of skin products containing alcohol may decrease the antibacterial action of pHisoHex.

**Overdose: Symptoms:** The accidental ingestion of pHisoHex in amounts from 30 to 120 mL has caused anorexia, vomiting, abdominal cramps, diarrhea, dehydration, convulsions, hypotension and shock, and in several reported instances has been fatal.

**Treatment:** If patients are seen early, the stomach should be evacuated by emesis or gastric lavage. Olive oil or vegetable oil (60 mL) may then be given to delay absorption of hexachlorophene, followed by a saline cathartic to hasten removal. Treatment is symptomatic and supportive; i.v. fluids (5% dextrose in physiologic saline solution) may be given for dehydration. Correct any other electrolyte derangement. If marked hypotension occurs, vasopressor therapy is indicated. Consider the use of opiates if gastrointestinal symptoms (cramping, diarrhea) are severe. Scheduled medical or surgical procedures should be postponed until the patient's condition has been evaluated and stabilized.

Animal Toxicity: The oral LD 50 of hexachlorophene in male rats is 66 mg/kg body weight, in females 56 mg/kg body weight, and in weanling rats 120 mg/kg body weight. In suckling rats (10-days old), it is 9 mg/kg body weight.

**Dosage:** To be used for scrubbing and washing following suggested procedure to effect thorough cleansing.

Surgical Hand Scrub: Wet hands and forearms with water. Apply approximately 5 mL of pHisoHex over the hands and rub into a copious lather by adding small amounts of water. Spread suds over hands and forearms and scrub well with a wet brush for 3 minutes, paying particular attention to the nails and interdigital spaces. A separate nail cleaner may be used. Rinse thoroughly under running water.

Apply 5 mL to hands again and scrub as above for another 3 minutes. Rinse thoroughly with running water and dry.

For repeat surgical scrubs during the day, scrub thoroughly with the same amount of pHisoHex for 3 minutes only. Rinse thoroughly with running water and dry.
Bacteriostatic Cleansing: Wet hands with water. Dispense approximately 5 mL of pHisoHex into the palm, work up a lather with water and apply to area to be cleansed.

Rinse thoroughly after each washing.

Infant care: pHisoHex should not be used routinely for bathing infants (see Precautions).

Premature Infants: (see Precautions).

Use of baby skin products containing alcohol may decrease the antibacterial action of pHisoHex.

pHisoHex should not be dispensed from, or stored in, containers with ordinary metal parts. Plastic or a special type of stainless steel must be used or undesirable discoloration of the product or oxidation of metal may occur.

Supplied: Each mL of white to slightly off-white emulsion contains: hexachlorophene 3%.

Nonmedicinal ingredients: Entsufon sodium, lanolin cholesterol, lauryl myristyl diethanolamide, methylcellulose, petrolatum (white), polyethylene glycol, polyethylene glycol monostearate, sodium benzoate and purified water.

pHisoHex is available in bottles of 150 mL and 450 mL.

STORAGE AND STABILITY

Temperature:
Store between 15 and 30ºC.

Others:
Avoid freezing.