

Notice on Amending the Instructions for Cold-clearing Preparation

China Food and Drug Administration

(Directive No.155 of 2016)

Sep 30, 2016

In accordance with the results of adverse drug reactions, in order to further protect the safety of public use, the China Food and Drug Administration has decided to revise the warning signs, [adverse reactions], [contraindications], [precautions] and medication for special patients.

Notice of the matter is as follows:

- I. All the manufacturers of cold-clearing preparations shall, based on the "Drug Registration Management Measures" and other relevant provisions, in accordance with the requirements of the cold vaccine's instructions (see Annex), propose the supplement to the revised instructions. And it has reported to the provincial food and drug regulatory authorities for the record before October 28, 2016.

If the amendment relates to drug label, it shall be revised together. The contents of instructions and labels shall be consistent with the original approved contents. Within 6 months after the application for supplement, it shall replace the exit-factory drug instructions and labels.

Each manufacturer of cold-clearing preparation shall carry out in-depth study on the mechanism of new adverse reactions, take effective measures to do a good job in the use of influenza and the use of safety and safety training and guide physicians to rational use of drugs.

- II. Clinicians shall carefully read the revised contents of cold-clearing preparation's instructions. In the case of medication, a sufficient benefit / risk analysis shall be carried out in accordance with the newly revised instructions.
- III. Cold-clearing preparations are prescription drugs. Patients shall be strictly prescribed for medication. Please read carefully the new revision of cold-clearing preparation's instructions before taking the medicine.

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China Food and Drug Administration

September 22, 2016

Annex:

**Requirements for revision of
cold-clearing preparation's instructions**

I. Warnings shall include:

This product is Chinese and western medicine compound preparation, containing chemical ingredients of acetaminophen, chlorobenzene maleate, morpholine guanidine hydrochloride.

II. [Adverse reactions] shall include:

1. Digestive system: nausea, vomiting, dry mouth, anorexia, stomach pain, hiccups, diarrhea, abdominal pain, abdominal distension, abdominal discomfort, elevated transaminase, abnormal liver biochemical indicators, etc.
2. Mental and nervous system: headache, dizziness, drowsiness, insomnia, hand, foot numbness, limitations of convulsions, low back pain, etc.
3. Skin and its accessories: rash, itching, etc.
4. Urinary system: individual report for hematuria, oliguria, polyuria, eyelid and facial edema, renal insufficiency case.
5. Blood system: acute neutropenia, thrombocytopenia, anemia, bleeding tendency, etc.
6. Body: fatigue, fever, chills, etc.
7. Other: chest tightness, sore throat, palpitations, flushing, tinnitus, hearing loss, etc.

III. [Contraindications] shall include:

1. It is known to be disabled in patients with allergies to this product or its ingredients.
2. Patients with a history of asthma, urticaria, or other allergic reactions caused by aspirin or other nonsteroidal anti-inflammatory drugs are forbidden to use.
3. Patients with a history of gastrointestinal bleeding or perforation caused by nonsteroidal anti-inflammatory drugs, patients with active gastrointestinal ulcers / bleeding, or patients who had previously relapsed ulcers / bleeding are forbidden to use.
4. Coronary artery bypass surgery (CABG) perioperative patients, patients with severe heart failure, severe liver and kidney dysfunction are forbidden to use.
5. This product contains chlorobenzene maleate: neonatal and preterm children, epilepsy patients, patients receiving monoamine oxidase inhibitors are forbidden to use; high-altitude operators, travel drivers, dangerous machinery operators forbidden to use during work.

renal failure performance;

- (6) interference to the diagnosis: ① blood glucose determination - the use of glucose oxidase / peroxidase method for determination may have false low value while the use of hexokinase / 6-phosphate dehydrogenase method for determination shall have no effect; ② determination of serum uric acid - the use of phosphotungstic acid method for determination may have false high value; ③ determination of urine 5-hydroxyindole acetic acid (5-HIAA) - the use of nitroso naphthol reagent for qualitative screening test may have false positive results but quantitative testing is not affected;
- (7) attention shall be paid to the interaction of acetaminophen with drugs that are combined: ① during the combined use of drugs that induce liver enzymes, such as certain hypnotics and antiepileptic drugs (glutethimide, phenobarbital, phenytoin, carbamazepine) or rifampicin, even the use of harmless amounts of acetaminophen may still cause liver damage. In the case of alcohol, even if the use of therapeutic doses of acetaminophen may still cause liver damage; ② long-term large amounts of aspirin, other salicylate preparations or other non-steroidal anti-inflammatory drugs in combination (such as the cumulative annual amount of 1000 g, the application of more than 3 years), can significantly increase renal toxicity (including renal papillary necrosis, kidney and Bladder cancer, etc.); ③ large or long-term use of acetaminophen, can reduce the coagulation factor in the liver synthesis, enhance the role of anticoagulants, therefore the amount of anticoagulant shall be adjusted according to prothrombin time; ④ simultaneous administration with chloramphenicol shall enhance the latter's toxicity; ⑤ the combination use of antiviral drug zidovudine shall, due to the combination effect of reduction with glucuronic acid to each other, decrease the clearance and increase the toxicity, so it shall avoid simultaneous use.

8. This product contains chlorobenzene maleate:

- (1) cross-allergic reactions: patients who are allergic to other antihistamines or the following drugs, may also be allergic to chlorobenzene maleate, such as ephedrine, epinephrine, isoproterenol, isoproterenol adrenaline (hydroxyl asthma), norepinephrine and other sympathomimetic drugs. The ones who are allergic to iodine may also allergic to chlorobenzene maleate;
- (2) infants, pregnant women, patients of angle-closure glaucoma, bladder neck obstruction, pyloric duodenal obstruction or peptic ulcer caused by pyloric stenosis, hyperthyroidism, hypertension, benign prostatic hyperplasia, cardiovascular disease and liver biochemical abnormalities shall be careful to the use of medication;
- (3) attention shall be paid to the interaction of chlorpheniramine maleate with the drug of the combination: ① medication while alcohol drinking or use of central nervous system inhibitors shall enhance antihistamine effect; ② it can enhance the role of amantadine, anticholinergics, haloperidol, phenothiazines and sympathomimetic drugs; it shall not be used together with drugs containing anticholinergic agents (such as belladonna preparations, atropine, etc.); ③ the use of quinidine shall make enhancement of similar effect of atropine sample; ④ the drug with

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