

Information for patients regarding a drug interaction between ritonavir (NORVIR®/KALETRA®) and fluticasone propionate (FLONASE®, FLOVENT®, ADVAIR®)

MISSISSAUGA, Ontario (January 27, 2004) – GlaxoSmithKline Inc. is informing patients of the results of a drug interaction study conducted with FLONASE® (fluticasone propionate) aqueous nasal spray and NORVIR® (ritonavir, Abbott Laboratories).

A recent clinical study in healthy volunteers found that concurrent administration of NORVIR® (ritonavir, Abbott Laboratories) and FLONASE® (fluticasone propionate, GlaxoSmithKline) aqueous nasal spray, an intranasal corticosteroid for allergies, resulted in greatly increased concentrations of fluticasone propionate in the blood. In addition, GlaxoSmithKline has received reports of adrenal suppression in patients who were taking ritonavir and fluticasone propionate simultaneously. Adrenal suppression is a condition in which the adrenal glands produce too little of the hormones required for the body's normal functioning, reducing the body's ability to heal, particularly after surgery, infection or serious injury. Therefore, ritonavir and fluticasone should only be taken together if the benefit to the patient outweighs the risk of adrenal suppression. Care should also be taken for patients who are taking other drugs that are known to affect fluticasone propionate metabolism, such as azole antifungals.

Ritonavir, a protease inhibitor used in the treatment of HIV/AIDS, is a potent inhibitor of the enzymes responsible for elimination of fluticasone propionate from the body. When taken together with some inhaled or intranasal corticosteroids, patients may be at risk of corticosteroid side effects, such as adrenal suppression. Inhaled or intranasal corticosteroids are used to treat allergies, asthma, and/or chronic obstructive pulmonary disease (COPD).

Other corticosteroid preparations are known to share the same elimination pathway as fluticasone propionate and could potentially be affected by the interaction with ritonavir, resulting in adverse events similar to that seen with fluticasone propionate. **HIV-infected patients who are also taking a corticosteroid preparation should contact their physician to discuss their current medications.**

Patients are advised that medications should not be stopped without consulting a physician. Abruptly stopping medications may result in deteriorating health, which may be life-threatening.

Fluticasone propionate is also contained in the products FLOVENT® (fluticasone propionate) inhalation aerosol and dry powder for inhalation, and ADVAIR® (salmeterol xinafoate/fluticasone propionate) inhalation aerosol and dry powder for inhalation, manufactured by GlaxoSmithKline.

GlaxoSmithKline has sent a letter to health care professionals in Canada informing them of the drug interaction between ritonavir and FLONASE® and of other potential interactions with inhaled or intranasal corticosteroids by the same pathway as fluticasone. This information may be obtained on the Canadian website of GlaxoSmithKline (<http://www.gsk.ca>) or on the website of the Therapeutic Products Directorate of Health Canada (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_public_e.html).

Suspected adverse reactions arising from the simultaneous use of ritonavir and fluticasone propionate can be reported directly to GlaxoSmithKline at the following address:

GlaxoSmithKline Inc.
7333 Mississauga Road N
Mississauga, Ontario
L5N 6L4
Tel: 1-800-387-7374

NORVIR[®] and KALETRA[®] are registered trademarks, used under license by Abbott Laboratories.

FLOXONASE[®], FLOVENT[®] and ADVAIR[®] are registered trademarks, used under license by GlaxoSmithKline Inc.

Any suspected adverse reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA

Address Locator: 0701C

OTTAWA, Ontario, K1A 0K9

Tel: (613) 957-0337 or Fax: (613) 957-0335

Toll free for consumers and health professionals:

Tel: (866) 234-2345, Fax: (866) 678-6789

cadtmp@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the TPD web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.