combination offers the advantages of convenience to patients and improved adherence for taking the medication at appropriate dose and intervals as prescribed (see, for example, *Pan et al., J. Gen. Intern. Med. 23(5): 611-4, 2008*). In particular, there is a need for a single combination product which is small enough that it can be swallowed easily by an adult, whilst being stable and whilst retaining the dissolution characteristics of the active components as found in the respective commercially available monotherapy products.

Summary

In one aspect, the present disclosure refers to a solid oral fixed dose composition comprising a bilayer part comprising

a. an extended release layer comprising metformin or a pharmaceutically acceptable salt thereof; and one or more excipients; and

b. an immediate release layer comprising valsartan or a pharmaceutically acceptable salt thereof and one or more excipients;

and further comprising

an immediate release coating layer comprising atorvastatin, or a pharmaceutically acceptable salt thereof; and one or more excipients.

In another aspect, the present disclosure refers to a solid oral fixed dose composition comprising a bilayer part comprising

a. an extended release layer comprising metformin hydrochloride in a unit dose strength of about 500 mg; and one or more excipients;

b. an immediate release layer comprising valsartan in a unit dose strength of about 80 mg; and one or more excipients;

and further comprising

an immediate release coating layer comprising atorvastatin calcium trihydrate in a unit dose strength of about 10 mg; and one or more excipients.

In a further aspect, the present disclosure refers to a process for preparing a solid oral fixed dose composition disclosed herein comprising forming a compressed bilayer part comprising:

a. an extended release layer comprising metformin, or a pharmaceutically acceptable salt thereof, and one or more excipients; and

b. an immediate release layer comprising valsartan, or a pharmaceutically acceptable salt thereof, and one or more excipients;

and coating with an immediate release coating layer comprising atorvastatin, or a pharmaceutically acceptable salt thereof, and one or more, excipients.

Description

Compositions of this invention provide a treatment that may improve glycemic control in patients in need thereof, and further simultaneously treat hyperlipidemia and/or hypertension that may be related to or caused by increased blood glucose, in a patient in need thereof.

The present invention is a single product oral composition comprising the three fixed dose pharmaceutically active ingredients metformin, atorvastatin, and valsartan or pharmaceutically acceptable salts thereof, wherein the composition comprises a bilayer part comprising a metformin layer and valsartan layer; and an immediate release atorvastatin coating. The present invention provides fixed dose compositions which are stable and which have desirable dissolution characteristics.

In particular, the present invention is a solid oral fixed dose composition comprising a bilayer part comprising

a. an extended release layer comprising metformin or a pharmaceutically acceptable salt thereof; and one or more excipients; and

b. an immediate release layer comprising valsartan or a pharmaceutically acceptable salt thereof and one or more excipients;

and further comprising an immediate release coating layer comprising atorvastatin, or a pharmaceutically acceptable salt thereof; and one or more excipients.

In an alternate embodiment, the present invention provides a solid oral fixed dose composition comprising:

a. an extended release layer comprising metformin hydrochloride XR or metformin hydrochloride; and one or more excipients;

b. an immediate release layer comprising valsartan and one or more excipients;

c. an immediate release coating layer comprising atorvastatin, or a pharmaceutically acceptable salt thereof; and one or more excipients.