Hemostatic foam

Field of the invention

The present invention relates to pharmaceutical hemostatic foam formulations.

Background of the invention

Foams are generally understood to represent materials in which a gas, such as air, is finely dispersed in a liquid in a form that is stable over some time. The liquid is found in the form of thin films between the bubbles. The stabilizing element of such gas dispersions is the surface tension of the liquid phase. The surface tension can be influenced by the presence of surface-active agents in the fluid phase, which help to stabilize the films against collapse. These foams are generally referred to as closed pore foams, as there is no connection between the gas spaces of each individual bubble. If the liquid films are stabilized by other means, e.g. by chemical reactions that transform the liquid phase into a viscoelastic solid, then the formation of open pore foams is possible, in which the fluid bridges are removed in a controlled manner, e.g. by evaporation or other processes. The transformation of the liquid films into a viscoelastic solid material also serves to effectively stabilize the foams against rapid collapse.

It is an object of the present invention to provide improved hemostatic foams which can be safely injected into tissue voids with low visibility and which are effective with no need for approximation. In addition, it is important that such a foam hemostat does not present a risk of obstruction or compression of pressure sensitive organs or tissues due to excessive swelling. Such a foam should be specifically applicable in neuro/spine, laparoscopic and cardiovascular surgery.

Summary ~~of the invention~~

Accordingly, ~~the~~ an aspect of the present ~~invention~~ disclosure is ~~provides~~ a pharmaceutical hemostatic liquid foam base preparation comprising albumin as

foaming agent and a fibrinogen precipitating substance and optionally a coagulation inducing agent, wherein albumin as foaming agent is present in native form.

Another aspect of the present ~~invention~~ disclosure is a method for preparing a pharmaceutical hemostatic liquid foam, wherein a pharmaceutical hemostatic liquid foam base preparation according to the present ~~invention~~ disclosure is contacted with a foaming gas so as to obtain a pharmaceutical hemostatic liquid foam.

Another aspect of the present ~~invention~~ disclosure is a transient pharmaceutical hemostatic liquid foam obtainable by a method according to the present ~~invention~~disclosure, preferably for use as a hemostat, especially for the treatment of wounds.

There is disclosed ~~Another aspect of the present invention is~~ a combination product, preferably a ready-to-use combination product, comprising a pharmaceutical hemostatic liquid foam base preparation according to the present ~~invention~~ disclosure and a foaming gas.

Another aspect of the present disclosure is a combination product, preferably a ready-to-use combination product, comprising a pharmaceutical hemostatic liquid foam base preparation according to the present disclosure and a foaming gas, preferably a foaming gas selected from the group consisting of air, N_2, O_2, N_2O, CO_2, or partly fluorinated hydrocarbons (HFCs), especially 1,1,1,2-Tetrafluoroethane (HFC134a) or 1,1,1,2,3,3,3-Heptafluoropropane (HFC227ea).

Another aspect of the present ~~invention~~ disclosure is a kit for producing a transient pharmaceutical hemostatic liquid foam according to the present ~~invention~~disclosure, comprising

(a) a first container comprising a pharmaceutical hemostatic liquid foam base preparation according to the present disclosure~~invention~~, and

(b) a second container containing a foaming gas.

Another aspect of the present disclosure ~~invention~~ is the use of a pharmaceutical preparation according to the present disclosure ~~invention~~ for the manufacture of a hemostat, especially a hemostat for the treatment of wounds.

Brief description of the figures

Fig. 1 shows the structure of skin (A), the view of created skin lesion (B) and application of flowable hemostatic foam according to the present invention (C).

Fig.2 shows the degree of Bleeding Scale Scores (Bleeding score:

0	no bleeding	-product saturated with blood
1	ooze	-blood out of product but no blood drop
2	very mild	-blood drop on the product