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Disturbi del sistema nervoso:

Nevralgia, parestesia, convulsioni febbrili, disturbi neurologici quali encefalomielite, nevriti e sindrome di Guillain Barré.

Disturbi vascolari:

Vasculiti associati in rari casi a interessamento renale transitorio.

Affezioni cutanee e del tessuto sottocutaneo:

Reazioni cutanee generalizzate, tra cui prurito, orticaria o rash aspecifico.

4.9 Sovradosaggio

E' improbabile che il sovradosaggio possa avere alcun effetto indesiderato.

5. PROPRIETA' FARMACOLOGICHE

5.1 Proprietà farmacodinamiche

Categoria farmacoterapeutica:Vaccino Influenzale, codice ATC: J07BB02.

La sieroprotezione si ottiene generalmente in 2-3 settimane. La durata dell'immunità postvaccinale a ceppi omologhi o a ceppi strettamente collegati con i ceppi del vaccino varia ma solitamente è di 6-12 mesi.

5.2 Proprietà farmacocinetiche

Non applicabile

5.3 Dati preclinici di sicurezza

Non applicabile

6. INFORMAZIONI FARMACEUTICHE

6.1 Elenco degli Eccipienti

Sodio cloruro

Potassio cloruro

Potassio fosfato monobasico

Sodio fosfato bibasico biidrato

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Magnesio cloruro esaidrato

Calcio cloruro biidrato

Acqua per preparazioni iniettabili.

6.2 Incompatibilità

In assenza di studi di compatibilità, questo prodotto medicinale non deve essere mescolato con altre preparazioni iniettabili.

6.3 Periodo di validità

1 anno

6.4 Precauzioni particolari per la conservazione

Conservare in frigorifero (2°C – 8°C). Non congelare. Tenere la siringa all'interno della scatola per proteggerla dalla luce.

6.5 Natura e contenuto del contenitore

0,5 ml di sospensione in una siringa pre-riempita (vetro di tipo I), con ago (23 G, 1'' o 25 G, 1'' o 25 G, 5/8''), con pistone munito di tappo di gomma, confezioni da 1 o da 10.

0,5 ml di sospensione in una siringa pre-riempita (vetro di tipo I), senza ago, con pistone munito di tappo di gomma, confezioni da 1 o da 10.

Non tutte le confezioni possono essere disponibili sul mercato

6.6 Precauzioni particolari per lo smaltimento e la manipolazione

Portare AGRIPPAL S1 a temperatura ambiente prima di somministrarlo. Agitare prima dell'uso.

Nel caso in cui debba essere somministrata metà dose (0,25 ml), prima dell'uso eliminare metà volume (fino al segno indicato sulla siringa).

Il medicinale non utilizzato ed i rifiuti derivati da tale medicinale devono essere smaltiti in conformità alla normativa locale vigente.

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, 53100 SIENA, Italia.

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8. NUMERO DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

AIC Numero: 026405264/M (con ago da 23 G, 1'', 1x); 026405340/M (con ago da 25 G, 1'', 1x); 026405353/M (con ago da 25 G, 5/8'', 1x); 026405276/M (senza ago, 1x); 026405288/M (con ago da 23 G, 1'', 10x); 026405326/M (con ago da 25 G, 1'', 10x); 026405338/M (con ago da 25 G, 5/8'', 10x); 026405290/M (senza ago, 10x).

9. DATA DI RINNOVO DELL'AUTORIZZAZIONE

22 gennaio 2009

10. DATA DI REVISIONE DEL TESTO:

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Rome 18 May 2010

A.N.M. FOLIO 10 MESA DE ENTRADAS

Logo
Italian Medicines Agency
AIFA
Evaluation and Registration Office

No.
Reply to Sheet dated.....
No. Ref. AIFA/V&A/no. 67603

To the Company:
Novartis Vaccines and Diagnostics s.r.l.,
Via Fiorentina 1,
53100 Siena (SI)

RE: **Communication of regular notification for changes to printed material**

File Code no. N1B/2010/2831
Medicinal product: AGRIPPAL S1
Packaging code
MA 026405264/M – "suspension for injection" 1 pre-filled syringe with needle of 23 G, 1"
MA 026405340/M – "suspension for injection" 1 pre-filled syringe with needle of 25 G, 1"
MA 026405353/M – "suspension for injection" 1 pre-filled syringe with needle of 25 G, 5/8"
MA 026405276/M – "suspension for injection" 1 pre-filled syringe without needle
MA 026405288/M – "suspension for injection" 10 pre-filled syringes with needle of 23 G, 1"
MA 026405326/M – "suspension for injection" 10 pre-filled syringes with needle of 25 G, 1"
MA 026405338/M – "suspension for injection" 10 pre-filled syringes with needle of 25 G, 5/8"
MA 026405290/M – "suspension for injection" 10 pre-filled syringes without needle
No. and type of variation
IT/H/0102/001/IB/062 Type IB foreseen
Nature of the change:
Harmonisation of the Summary of Product Characteristics and the Patient Information Leaflet pursuant to the model of the CMDh for trivalent influenza vaccines

Considering the notification sent to this Company pursuant to the Regulation (EC) no. 1234/2008 of the European Commission regarding the change to the printed material indicated above;
Considering the controls performed by this Office;

the notification itself is to be considered regular. Consequently the requested change to the printed material is authorised (paragraphs 2, 4.3 and 6.6 of the Summary of Product Characteristics and the corresponding paragraphs of the Patient Information Leaflet in order to harmonise the SPC and PIL pursuant to the model of the CMDh for trivalent influenza vaccines) in relation to the packaging listed above and responsibility is deemed entrusted to the Company holder of the MA. The Summary of Product Characteristics and the Patient Information Leaflet, corrected and approved, are enclosed with this Notification.

Considering the notification of end of procedure IT/H/0104/001/R/02 transmitted by the competent Italian authority in its capacity as Reference Member State (RMS); the authorisation of the medicinal product is amended, in conformity with the enclosure which represents an integral part of this notification, as indicated below:

Harmonisation of the Summary of Product Characteristics and the Patient Information Leaflet pursuant to the model of the CMDh for trivalent influenza vaccines (changes to paragraphs 2, 4.3 and 6.6 of the Summary of Product Characteristics and the corresponding paragraphs of the Patient Information Leaflet)

The Holder of the Marketing Authorisation must make the necessary changes to the Summary of Product Characteristics and the Patient Information Leaflet from the date of this notification coming into force.
The batches already manufactured can no longer be dispensed to the public starting from the 90th day following that of publication of this resolution in the Gazzetta Ufficiale (Official Journal) of the Italian Republic.
Following the aforementioned deadline only packages bearing the authorised changes may be dispensed to the public.

The packaging name to be indicated on the printed material as specified above, in accordance with the list of standard terms of the European Pharmacopoeia, is also approved.
In compliance with Legislative Decree no. 283/2001, article 14, the original of the sworn translation of the printed material in German must also be submitted, enclosed with a declaration by the legal representative confirming that the printed material drafted in German corresponds precisely to the amended Italian versions.
This Company is also bound to publish the extract of this change in the Gazzetta Ufficiale (Official Journal) of the Italian Republic within 15 days of the date of notification. The efficacy of the deed runs from the day following that of its publication.

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THE DIRECTOR
Dr. Anna Rosa Marra
[*Signature*]

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AGRIPPAL S1, Suspension for injection in pre-filled syringe

Influenza vaccine (surface antigen, inactivated)

(2009/2010 SEASON)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase), of the following strains*:

A/Brisbane/59/2007 (H1N1) – derived strain used A/Brisbane/59/2007, IVR-148
15 micrograms HA**

A/Brisbane/10/2007 (H3N2) – like strain used A/Uruguay/716/2007, NYMC X-175C derived from A/Uruguay/716/2007,
15 micrograms HA**

B/Brisbane/60/2008
15 micrograms HA**

Per 0.5 ml dose

* propagated in fertilized hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (northern hemisphere) and EU decision for the 2009/2010 season.

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.

The vaccine appears as a clear liquid.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza, especially in those who run an increased risk of associated complications.

The use of AGRIPPAL S1 should be based on official recommendations.

4.2 Posology and method of administration

Adults and children from 36 months: 0.5 ml

Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

For instructions for preparation, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients and to residues, e.g. eggs, chicken proteins, such as ovalbumin.

The vaccine may contain residues of the following substances, e.g. eggs, chicken proteins kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) and polysorbate 80.

Immunisation shall be postponed in patients with febrile illness or acute infection.

4.4 Special warnings and special precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

AGRIPPAL S1 should under no circumstances be administered intravascularly.

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Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

4.5 Interactions with other medicinal products and other forms of interaction

AGRIPPAL S1 may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Pregnancy and lactation

The limited data from vaccinations in pregnant women do not indicate that adverse foetal and maternal outcomes were attributable to the vaccine. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.

AGRIPPAL S1 may be used during lactation.

4.7 Effects on ability to drive and use machines

AGRIPPAL S1 is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS

The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 – 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:
Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000), including isolated reports.

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Nervous system disorders
Common (≥1/100, <1/10):
Headache*

Skin and subcutaneous tissue disorders
Common (≥1/100, <1/10):
Sweating*

Musculoskeletal and connective tissue disorders
Common (≥1/100, <1/10):
Myalgia, arthralgia*

General disorders and administration site conditions
Common (≥1/100, <1/10):
Fever, malaise, shivering, fatigue.
Local reactions: redness, swelling, pain, ecchymosis, induration.*

*These reactions usually disappear within 1-2 days without treatment.

ADVERSE REACTIONS REPORTED FROM POST-MARKETING SURVEILLANCE

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:
Neuralgia, paraesthesiae, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain-Barré syndrome

Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash

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4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02.
Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

1 year.

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6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of the container

0.5 ml of suspension in pre-filled syringe (type I glass) with needle (23 G, 1" or 25 G, 1" or 25 G, 5/8"), equipped with a rubber plunger stopper – pack size of 1 or 10.
0.5 ml of suspension in pre-filled syringe (type I glass) without needle, equipped with a rubber plunger stopper – pack size of 1 or 10.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

AGRIPPAL S1 should be allowed to reach room temperature before use.

Shake before use.

If half a dose (0.25 ml) is to be administered, discard half the contained volume (up to the mark indicated on the syringe barrel), before injection.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Novartis Vaccines and Diagnostics S.r.l., Via Fiorentina 1, 53100 SIENA, Italy

8. MARKETING AUTHORISATION NUMBER

MA number: 026405264/M (with needle of 23G, 1'', 1x); 026405340/M (with needle of 25 G, 1'', 1x); 026405353/M (with needle of 25G, 5/8'', 1x); 026405276/M (without needle, 1x); 026405288/M (with needle of 23G, 1'', 10x); 026405326/M (with needle of 25G,1'', 10x); 026405338/M (with needle of 25G, 5/8'', 10x); 026405290/M (without needle, 10x).

9. DATE OF RENEWAL OF AUTHORISATION

22 January 2009

10. DATE OF REVISION OF TEXT

The Translator

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CRON. N. 1526/2010

TRIBUNALE DI SIENA

L'anno 2010 e questo Dì 25 Ottobre, Avanti il sottoscritto Cancelliere è personalmente comparsa la Sig.ra Maria Teresa Malatesta, nata a Siena il 15.09.1974 residente a Siena, Via Aretina n. 139, Patente di guida n. SI2164961W rilasciata dalla Prefettura di Siena e valida fino al 14/02/2013, la quale presenta la traduzione che precede, dichiarando di confermarla e ratificarla in ogni sua parte e di volerla asseverare mediante giuramento.

Ammonita a norma di legge la richiedente giura ripetendo la formula:

"GIURO DI AVER BENE E FEDELMENTE ADEMPIUTO ALLA OPERAZIONE AFFIDATAMI E DI NON AVER AVUTO ALTRO SCOPO CHE QUELLO DI FAR CONOSCERE AI GIUDICI LA VERITA' ".

Letto, confermato e firmato

IL CANCELLIERE

SIENA CIVIL COURT

On this 25th day of October, Ms. Maria Teresa Malatesta born in Siena (Italy) on 15.09.1974, resident in Siena, Via Aretina n. 139, Drive License n. SI2164961W issued by the Prefettura of Siena and expiring on 14/02/2013, has personally appeared before this Legislative Branch Officer submitting the here enclosed translation, which is entirely confirmed and ratified by herself. She asks to certify this translation under oath.

According to current laws, the undersigned translator swears by repeating the following:

"I SWEAR TO HAVE FAITHFULLY CARRIED OUT TO THE BEST OF MY KNOWLEDGE, THE TRANSLATION GIVEN TO ME AND TO HAVE NO OTHER INTENTION THAN LETTING THE JUDGE KNOW THE TRUTH"

The translator

THE LEGISLATIVE OFFICER

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Apoderada

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CROM. 1526 ANMAT FOLIO 88 MESA DE ENTRADAS

CHTEL
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LÉS
PITAL FEDERAL
A. Nro. 2420

MIRIAM F.
TRADUCTOR
IDIOMA
MAT. Tº IX - Fº 277
INSCRIP. C.T.P.

TRIBUNALE DI SIENA

VERBALE DI GIURAMENTO

anno 2010 e questo di 25 del mese di OTTOBRE

Avanti il sottoscritto Cancelliere è personalmente comparso

il sig. [illegible] il 15/09/1974, [illegible] n° 139. Patente n° SI-2164961 W rilasciata il 8/03/1993 dalla Prefettura di Siena.

il quale presenta la ~~perizia~~ (o traduzione) che precede, dichiarando di confermarla e ratificarla in ogni sua parte e di volerla asseverare mediante giuramento.

Ammonito a norma di legge il richiedente giura ripetendo la formula: «GIURO DI AVER BENE E FEDELMENTE ADEMPIUTO ALLE OPERAZIONI AFFIDATEMI E DI NON AVER AVUTO ALTRO SCOPO CHE QUELLO DI FAR CONOSCERE AI GIUDICI LA VERITA'».

Letto, confermato e firmato

[signature]

IL CANCELLIERE

IL DIRETTORE AMMINISTRATIVO
(Dott.ssa Stefania Tempesti)

TRIBUNALE DI SIENA

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FOLIO

MESA DE ENTRADAS

PROCURA DELLA REPUBBLICA
presso il Tribunale Ordinario di SIENA

APOSTILLE

(Convenzione dell' Aja del 5-10-1961)

Paese ITALIA

Il presente atto pubblico è stato sottoscritto dal

Tenledi Stefanie

agente in qualità di Direttore Amministrativo

ed è segnato dal contrassegno / timbro

" Tribunale Siena "

ATTESTATO

a Siena il 25 gennaio 2010 dal Procuratore della Repubblica di Siena, sotto il numero 638/10 Reg. Apostille.

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A.N.M.A.T FOLIO 90 MESA DE ENTRADAS

TRADUCCIÓN PÚBLICA----------

[Aparece texto en idioma desconocido]----------

Roma, 18 de Mayo de 2010----------

Logo----------

Agencia Italiana de Medicamentos----------

AIFA----------

Oficina de Evaluación y Registro----------

No. Respuesta a foja de fecha ----------

No. Ref. AIFA/V&A/No. 67603----------

A la compañía: ----------

Novartis Vaccines and Diagnostics S.r.l.----------

Via Fiorentina 1,----------

53100 Siena (SI)----------

REF: Comunicación de notificación regular para cambios en el material impreso----------

Código de Archivo N° N1B/2010/2831----------

Medicamento: AGRIPPAL S1----------

Código de Envase----------

MA 026405264/M - "suspensión inyectable" 1 jeringa precargada con aguja de 23 G, 1"----------

MA 026405340/M - "suspensión inyectable" 1 jeringa precargada con aguja de 25 G, 1"----------

MA 026405353/M - "suspensión inyectable" 1 jeringa precargada con aguja de 25 G, 5/8"----------

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MA 026405276/M - "suspensión inyectable" 1 jeringa precargada sin aguja----------

MA 026405288/M - "suspensión inyectable" 10 jeringas precargadas con aguja de 23 G, 1"----------

MA 026405326/M - "suspensión inyectable" 10 jeringas precargadas con aguja de 25 G, 1"----------

MA 026405338/M - "suspensión inyectable" 10 jeringas precargadas con aguja de 25 G, 5/8"--------

MA 026405290/M - "suspensión inyectable" 10 jeringas precargadas sin aguja----------

N° y tipo de variación----------

IT/H/0102/001/IB/062 Tipo IB previsto----------

Naturaleza del cambio:----------

Armonización del Resumen de Características del Producto y el Folleto de Información para el Paciente de conformidad con el modelo de CMDh para vacunas antigripales trivalentes----------

---

Considerando la notificación enviada a esta Compañía de conformidad con la Regulación (EC) N° 1234/2008 de la Comisión Europea con respecto al cambio en el material impreso indicado anteriormente;----------

Considerando los controles realizados por esta Oficina; ----------

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la notificación en sí se considera regular. En consecuencia se autoriza el cambio solicitado en el material impreso (párrafos 2, 4.3 y 6.6 del Resumen de Características del Producto y párrafos correspondientes del Folleto de Información para el Paciente con el fin de armonizar el Resumen de Características del Producto y el Folleto de Información para el Paciente de conformidad con el modelo de CMDh para vacunas antigripales trivalentes) en relación con los envases listados anteriormente y se considera al titular de la Autorización de Comercialización de la Compañía a cargo de la responsabilidad. El Resumen de Características del Producto y el Folleto de Información para el Paciente, corregidos y aprobados, se adjuntan con esta Notificación. ------

Considerando la notificación de finalización del procedimiento IT/H/0104/001/R/02 transmitida por la autoridad competente italiana en su calidad de Estado Miembro de Referencia (RMS); se enmienda la autorización del medicamento, de conformidad con el anexo que representa una parte integrante de la presente notificación, según se indica a continuación: ----------

Armonización del Resumen de Características del Producto y el Folleto de Información para el

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Paciente de conformidad con el modelo de CMDh para vacunas antigripales trivalentes (cambios en los párrafos 2, 4.3 y 6.6 del Resumen de Características del Producto y los párrafos correspondientes del Folleto de Información para el Paciente).----------

El Titular de la Autorización de Comercialización debe hacer los cambios necesarios en el Resumen de las Características del Producto y el Folleto de Información para el Paciente a partir de la fecha en que esta notificación entre en vigencia. --------

Los lotes ya fabricados no pueden dispensarse más al público a partir de los 90 días siguientes a la publicación de esta resolución en la Gazzetta Ufficiale (Boletín Oficial) de la República Italiana. ----------

Después de la fecha límite mencionada sólo pueden dispensarse al público envases que lleven los cambios autorizados. ----------

Se aprueba también el nombre del envase a indicar en el material impreso según lo especificado anteriormente, de acuerdo con la lista de términos estándar de la Farmacopea Europea. ----------

En cumplimiento con el Decreto Legislativo N° 283/2001, artículo 14, también debe presentarse el original de la traducción pública del material

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impreso en alemán, junto con una declaración del representante legal que confirme que el material impreso redactado en alemán corresponde precisamente a las versiones enmendadas en italiano. ----------

Esta Compañía también está obligada a publicar el extracto de este cambio en la Gazzetta Ufficiale (Boletín Oficial) de la italiana República dentro de los 15 días siguientes a la fecha de notificación. La eficacia de la acción se ejecuta a partir del día siguiente al de su publicación. ---

EL DIRECTOR ----------

Dra. Rosa Ana Marra ----------

[Firma] ----------

Agrippal S1 - Novartis Vaccines and Diagnostics S.r.l.----------

SPC - IT----------

Junio de 2009----------

Confidencial

RESUMEN DE LAS CARACTERÍSTICAS DEL PRODUCTO---------

1. NOMBRE DEL MEDICAMENTO----------

AGRIPPAL S1, Suspensión inyectable en jeringa precargada----------

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Vacuna antigripal (antígeno de superficie, inactivado) ----------

(TEMPORADA 2009/2010) ----------

2. COMPOSICIÓN CUALITATIVA Y CUANTITATIVA----------

Antígenos de superficie de virus de la gripe (hemaglutinina y neuraminidasa), de las siguientes cepas*:----------

A/Brisbane/59/2007 (H1N1) -cepa derivada utilizada A/Brisbane/59/2007, IVR-148----------

15 microgramos de HA**----------

A/Brisbane/10/2007 (H3N2) - cepa análoga utilizada A/Uruguay/716/2007, NYMC X-175C derivada de A/Uruguay/716/2007,----------

15 microgramos de HA**----------

B/Brisbane/60/2008----------

15 microgramos de HA**----------

Por dosis de 0,5 ml ----------

* propagada en huevos de gallina fecundados procedentes de bandadas de pollos sanos----------

** hemaglutinina----------

Esta vacuna cumple con las recomendaciones de la OMS (hemisferio norte) y el dictamen de la Unión Europea para la temporada 2009/2010.----------

Para una lista completa de excipientes ver sección 6.1 ----------

3. FORMA FARMACÉUTICA----------

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