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Levact® 2,5 mg/ml
25 mg, 5 flacons 343,64 Euro
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100 mg, 5 flacons 1.374,55 Euro

REIMBURSED

Levact®

bendamustine HCl

Designed to make a difference

Levact® is licensed for:

- First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate
- Indolent non-Hodgkin's lymphomas as monotherapy in patients, who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen
- Front-line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment

VERKORTE SAMENVATTING VAN DE PRODUCTKENMERKEN

Naam van het geneesmiddel: Levact® 2,5 mg/ml, poeder voor concentraat voor oplossing voor infusie. Therapeutische indicaties: Eerstelijns behandeling van chronische lymfatische leukemie (Binet stadium B of C) bij patiënten voor wie fludarabine combinatie therapie niet geschikt is. Indolente non-Hodgkin lymfomen als monotherapie bij patiënten die progressie vertoonden gedurende of binnen 6 maanden na behandeling met rituximab of een rituximab bevattende schema. Eerstelijns behandeling van multipel myeloom (Durie-Salmon stadium II met progressie of stadium III) in combinatie met prednison voor patiënten ouder dan 65 jaar die niet in aanmerking komen voor een autologe stamcel transplantatie en die tijdens de diagnose een klinische neuropathie hebben die een thalidomide of bortezomib bevattende behandeling verhindert. Contra-indicaties: Overgevoeligheid voor het werkzame bestanddeel of andere hulpstoffen (zie rubriek 6.1), gedurende borstvoeding, ernstige leverfunctiestoornissen (serum bilirubine > 3,0 mg/dl), geelzucht, ernstige beenmergsuppressie en ernstige bloedbeeldveranderingen (leucocyt en/of plaatjesvaarrendalen tot respectievelijk < 3.000/µl of < 75.000/µl), grote operaties binnen 30 dagen voor aanvang van de behandeling, infecties, vooral met leukocytopenie, inenting tegen gele koorts. Bijwerkingen: Zie vaak (>1/10): infectie NAS*, leukopenie NAS*, trombocytopenie, misselijkheid, braken, mucosale ontstekingen, vermoeidheid, koorts, hemoglobine afname, creatinine toename, urea toename. Vaak (>1/100, <1/10): tumor lysis syndroom, bloedingen, anemie, neutropenie, overgevoeligheid NAS*, slapeloosheid, cardiale dysfunctie zoals palpitations, angina pectoris, arrhythmie, hypertensie, hypertensie, pulmonaire dysfunctie, diarree, constipatie, stomatitis, alopecia, huidandoeningen NAS*, amenorrhoea, pijn, rillingen, dehydratie, anorexie, AST toename, ALT toename, alkaline phosphatase toename, bilirubine toename, hypokaliëmie. Soms (>1/1000 tot <1/100): pericardiale effusie. Zelden (≥ 10, 000 tot <1/1, 000): sepsis, anafylactische reactie, anafylactische reactie, suifheid, afonie, acute circulair falen, erythem, dermatitis, pruritus, huiduitslag: macula of papula, hyperhidrosis. Zeer zelden (<1/10, 000): atypische primaire pneumonie, hemolyse, anafylactische shock, dysgeusie, paresthesie, perifere sensorische neuropathie, anticholinergisch syndroom, neurologische aandoeningen, ataxie, encéfalitis, tachycardie, myocard infarct, hartfalen, flebitis, pulmonaire fibrose, hemorrhagische oesofagitis, gastrointestinale bloedingen, onvruchtbaarheid, multi-orgaan falen. * NAS = niet anders gespecificeerd. Zie verder volledige SPC. Dosering en wijze van toediening: Voor intraveneuze infusie gedurende 30 tot 60 minuten (zie rubriek 6.6). Monotherapie voor chronische lymfatische leukemie: 100 mg/m² lichaamsoppervlak bendamustine hydrochloride op dag 1 en 2; iedere 4 weken. Monotherapie voor indolente non-Hodgkin lymfomen die niet reageren op rituximab: 120 mg/m² lichaamsoppervlak bendamustine hydrochloride op dag 1 en 2; iedere 3 weken. Multipel myeloom: 120-150 mg/m² lichaamsoppervlak bendamustine hydrochloride op dag 1 en 2, 60 mg/m² lichaamsoppervlak prednison i.v. of per os op dag 1 tot 4; iedere 4 weken. Zie verder volledige SPC. Pediatriche patiënten: Er is geen ervaring bij kinderen en adolescenten met Levact®. Voor speciale patiëntengroepen, zie volledige SPC. Verpakkingen: 5, 20 flacons met 25 mg, 5 flacons met 100 mg. Houder van de vergunning voor het in de handel brengen: Astellas Pharma GmbH, Georg-Brauchle-Ring 64-66, D-80992 München, Duitsland. Nummer(s) van de vergunning voor het in de handel brengen: Levact® 2,5 mg/ml (25 mg), BE376013, Levact® 2,5 mg/ml (100 mg), BE376022. Alleen op medisch voorschrift. Datum van goedkeuring van de volledige SPC: augustus 2010.

RESUME COURT DES CARACTERISTIQUES DU PRODUIT

Dénomination du médicament: Levact® 2,5 mg/ml, poudre pour solution à diluer pour perfusion. Dénominations thérapeutiques: Traitement de première ligne de la leucémie lymphoïde chronique (stade Binet B ou C) des patients chez qui une polychimiothérapie comportant de la fludarabine n'est pas appropriée. Traitement en monothérapie du lymphome non hodgkinien indolent en progression, pendant ou dans les 6 mois, chez des patients ayant reçu un traitement par rituximab seul ou en association. Traitement de première ligne du myélome multiple (stade II évolutif ou stade III de la classification de Durie et Salmon) en association avec la prednisone chez des patients de plus de 65 ans qui ne sont pas éligibles pour la greffe autologue de cellules souches et qui présentent une neuropathie au moment du diagnostic excluant l'utilisation de traitement comportant du thalidomide ou du bortezomib. Contre-indications: Hypersensibilité au chlorhydrate de bendamustine ou à l'un des excipients (voir section 6.1), allaitement, insuffisance hépatique sévère (bilirubine sérique > 3,0 mg/dl), ictère, myélosuppression sévère et anomalie importante de la numération formule sanguine (le taux de leucocytes et/ou de plaquettes respectivement < 3 000/µl ou < 75 000/µl), intervention chirurgicale lourde moins de 30 jours avant le début du traitement, infections, notamment en cas de leucopénie, vaccination contre la fièvre jaune. Effets indésirables: Très fréquent (≥1/10): infection SAP*, leucopénie SAP*, thrombopénie, nausées, vomissement, inflammation des muqueuses, fatigue, fièvre, diminution du taux d'hémoglobine, augmentation de la créatinine et de l'urée. Fréquent (≥1/100, <1/10): syndrome de lyse tumorale, hémorragie, anémie, neutropénie, réaction d'hypersensibilité SAP*, insomnie, troubles cardiaques, telles que palpitations et angine de poitrine, arythmie, hypotension, hypertension, insuffisance pulmonaire, diarrhée, constipation, stomatite, alopecie, troubles cutanés SAP*, aménorrhée, douleur, frissons, déshydratation, anorexie, augmentation du taux des ASAT/ALAT, des phosphatases alcalines, de la bilirubine, hypokaliémie. Peu fréquent (≥1/1000 à <1/100): épanchement péricardique. Rare (≥1/10 000 à <1/1000): sépticémie, réaction anaphylactique, réaction anaphylactoïde, somnolence, anémie, insuffisance circulatoire aiguë, érythème, dermatite, prurit, éruption maculo-papuleuse, rash, hyperhidrose. Très rare (<1/10000): pneumopathie atypique primaire, hémolyse, choc anaphylactique, dysgueusie, paresthésie, neuropathie sensorielle périphérique, syndrome anticholinergique, troubles neurologiques, ataxie, encéphalite, tachycardie, infarctus du myocarde, insuffisance cardiaque, phlébite, fibrose pulmonaire, hémorragie oesophagienne, hémorragie digestive, infertilité, défaillance multi-organe. *SAP : sans autre précision. Pour plus d'informations, consultez le SPC complet. Posologie et mode d'administration: Pour perfusion intraveineuse de 30 à 60 minutes par voie intraveineuse (voir section 6.6). Leucémie lymphoïde chronique en monothérapie: 100 mg/m² de surface corporelle de chlorhydrate de bendamustine à jour 1 et jour 2; toutes les 4 semaines. Lymphomes non hodgkinien indolents en monothérapie chez les patients réfractaires au rituximab: 120 mg/m² de surface corporelle de chlorhydrate de bendamustine à jour 1 et jour 2; toutes les 3 semaines. Myélome multiple: 120-150 mg/m² de surface corporelle de chlorhydrate de bendamustine à jour 1 et jour 2, prednisone 60 mg/m² IV ou per os de jour 1 à jour 4; toutes les 4 semaines. Pour plus d'informations, consultez le SPC complet. Pédiatrie: Il n'y a pas d'expérience chez l'enfant et l'adolescent avec Levact®. Pour les groupes de patients spéciaux, consultez le SPC complet. Emballage: 5, 20 flacons à 25 mg, 5 flacons à 100 mg. Titulaire de l'autorisation de mise sur le marché: Astellas Pharma GmbH, Georg-Brauchle-Ring 64-66, D-80992 Munich. Numéro(s) d'autorisation de mise sur le marché: Levact® 2,5 mg/ml (25 mg), BE376013, Levact® 2,5 mg/ml (100 mg), BE376022. Sur prescription médicale. Date d'approbation du SPC complet: août 2010.





27th General Meeting of the Belgian Hematological Society

Final Program



January 27 - 28, 2012

Palais des Congrès

Liège

Accreditation pending

New website
www.bhs.be

SCIENTIFIC COMMITTEE: BHS BOARD

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Marc André, meeting coordinator
Axelle Gilles, educational program coordinator
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INTRODUCTION

Dear members of the BHS,

The Belgian Hematological Society is happy to welcome you to its 27th General Annual Meeting (GAM).

The GAM is a unique opportunity for scientists and clinicians interested in haematology research and in the care of patients affected with blood diseases to meet colleagues and friends, to attend state-of-the art presentations and to share ongoing laboratory and clinical research activities. This is a great opportunity for interaction and continuing education.

As usual, the GAM will feature:

- lectures by a distinguished panel of Belgian and foreign speakers on topics such as : treatment of relapsed Hodgkin's or diffuse large B-cell lymphoma; primary immunodeficiencies; hematopoietic stem cells and stem cell plasticity. This year, a special focus will be centered on MDS with 3 lectures on classification & prognosis, treatment, and paediatric MDS;
- oral presentations selected from submitted abstracts (4 clinical and 4 basic science abstracts);
- satellite symposia: one sponsored by Gilead on fungal infections, a second one by Roche on minimal residual disease in indolent lymphoma, and a third one by The Binding Site on the use of the Freelite assay and on Waldenström macroglobulinaemia.

We will also continue innovations proposed with great success last year:

- on Friday afternoon, there will be a parallel session for nurses. Indeed, this session last year met with considerable success and nurses willingness to build on this first experience was evident. This year they will constitute a new BHS Nurses Committee;
- we will again organize poster walks: posters will be divided into 6 broad topics, with a chairman for each topic conducting short presentations by authors followed by a discussion with the audience. This year, each topic will be presented only once and participants will have more time to interact with authors.

We will again conduct a truly interactive business meeting in the middle of the Saturday morning session and we would really like to encourage participants in the BHS meeting to attend. The business meeting will be devoted to:

- changes in the statutes of the BHS that have to be approved by the general assembly;
- presentations by BHS committee chairs of the work of their committee;
- presentations by the board of new projects, such as new membership categories, a brand new website, a renewed BHS course, installment of a BHS clinical research assistant, adoption of the Belgian Journal of Hematology as our official platform, creation of a Hematology Registry and a Transplant Registry, adoption of a central location for all BHS activities...

Finally, we are organizing a BHS diner on the Friday evening at the Palais des Congrès in Liège, an unique opportunity to meet colleagues in a friendly atmosphere.

Indeed, the board of the BHS is very enthusiastic to share with you its projects for the society.

We thank you for your presence in Liège and your participation in the BHS General Annual Meeting and other activities of the society.

*On behalf of the board,
Yves Beguin
President of the BHS*



VIROPHARMA

PROGRAM

Friday 27 January 2012

08.00 Welcome and registration
09.15 Opening

09.30 - 10.30 **Special highlight 1: lymphoma**

Chairmen: *Marc André, Anne Sonet*

09.30 Treatment of relapsed DLBCL
C. Gisselbrecht (Paris, France)
10.00 Treatment of relapsed Hodgkin's lymphoma
P. Borchman (Köln, Germany)

10.30 - 10.50 Coffee break

10.50 - 12.30 **Selected oral presentations**

Chairmen: *Rik Schots, Axelle Gilles*

- 10.50 Influence of pre-analytical storage conditions on quantitative BCR-ABL results in CML: a multi-centre study
S. Franke (CHU Liège)
- 11.02 Ponatinib is active against imatinib resistant mutants of FIP1L1-PDGFR α and KIT, and against FGFR1-derived fusion kinases
E. Lierman (KUL, Leuven)
- 11.14 Single-center analysis of biopsy-confirmed posttransplant lymphoproliferative disorder: final analysis
D. Dierickx (KUL, Leuven)
- 11.26 The accuracy of PET in detection of Posttransplant Lymphoproliferative Disorder
D. Dierickx (KUL, Leuven)
- 11.38 Positive selection of CD8 T cells in vitro is not dependent on MHC or CD1 expression
G. Verstichel (UZ Gent)
- 11.50 Rapamycin prevents experimental sclerodermatous chronic graft-versus-host disease in mice
L. Belle (CHU Liège)
- 12.02 Retrospective analysis on the impact of iron chelation therapy on survival and leukemia progression in transfusion dependent MDS patients in Belgium
M. Delforge (UZ Leuven)
- 12.14 Quantitative and qualitative analysis of metabolic response at interim FDG pet-scan is highly predictive of outcome in diffuse large B-cell lymphoma (DLBCL)
N. Nols (UCL Saint-Luc/Mont Godinne)

12.30 - 13.30 Lunch

**13.30 - 14.30 Satellite Symposium: Fungal infections
Sponsored by Gilead**

Chairmen: *Johan Maertens, Anne Sonet*

13.30 EORTC/MSG definitions in daily clinical practice:

Care Pathways

R. Barnes (Cardiff, UK)

14.00 Antifungals and the rationale of reimbursement in Belgium

J. Maertens (Leuven)

**14.30 - 15.00 Recent advances in Severe Combined
Immune Deficiency**

Chair: *Johan Maertens*

L. Notarangelo (Boston, USA)

15.00 - 15.40 Commented poster walk

15:40 - 16.00 Coffee break

16.00 - 17.00 Special highlight 2: stem cells

Chairmen: *Tessa Kerre, Yves Beguin*

16.00 Pierre Strijckmans lecture

Regulation of Hematopoietic Stem Cells and their Bone-Marrow
Niches by the Coagulation System

T. Lapidot (Rehovot, Israel)

16.30 Stem cell plasticity

P. Vanderhaeghen (Brussels)

**17.00 - 18.00 Satellite Symposium: Minimal residual disease in indolent
lymphoma**

Sponsored by Roche

Chairmen: *Fritz Offner, Eric Van Den Neste*

17.00 MRD in CLL: How low should we go?

P. Hillmen (Leeds, UK)

17.30 MRD detection in indolent lymphomas:

clinical implications and future perspectives

C. Pott (Kiel, Germany)

18.00 Reception

19.30 Diner

Saturday 28 January 2012

08.30 Welcome and registration

09.00 - 10.30 **Special highlight: MDS**

Chairmen: *Valérie Robin, Dominik Selleslag*

09.00 Classification and prognosis of MDS
U. Germing (Dusseldorf, Germany)

09.30 Treatment of MDS
P. Fenaux (Lille, France)

10.00 MDS in children
C. Niemeyer (Freiburg, Germany)

10.30 - 11.10 **Business meeting**

11.10 - 11.30 Coffee break

11.30 - 12.30 **Satellite Symposium: monoclonal gammopathies Sponsored by The Binding Site**

Chair: *Michel Delforge*

11.30 The use of the Freelite™ assay in various conditions
O. Decaux (Rennes, France)

12.00 Waldenström macroglobulinemia
X. Leleu (Lille, France)

12.30 Conclusion, awards & lunch



SPONSORS AND EXHIBITORS

Major sponsors

Amgen
The Binding Site
Gilead Sciences
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Exhibitors

Alexion Pharmaceuticals
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Miltenyi Biotec
Mundipharma
Novartis
Octapharma
Pfizer
Roche
Shire
Teva Pharma
Vifor Pharma
ViroPharma

EXHIBITION

A targeted group of pharmaceutical companies are invited to expose their products and services. Please note that the booths of pharmaceutical companies are meant for medical doctors only (regulations by Belgium Law).

GENERAL INFORMATION

Location

Palais des Congrès
Esplanade de l'Europe 2
4020 Liège
www.palaisdescongresliege.be

Registration and payment

Affiliate member (nurses, technicians, psychologists, data managers)	15 Eur
Associate member (residents, trainees, PhD students)	45 Eur
Member	75 Eur
Non-member	200 Eur
Membership Fees	
Affiliate member (nurses, technicians, psychologists, data managers)	10 Eur
Associate member (residents, trainees, PhD students)	40 Eur
Member	75 Eur

The registration fee includes admission to the meeting, programme / abstract book, certificate of attendance, coffee breaks and lunch.

Meeting language

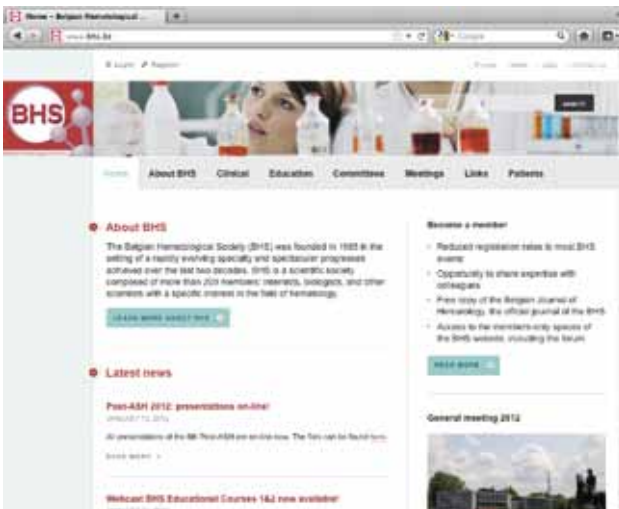
The meeting language will be English

Accreditation

Accreditation for the 27th Annual Meeting of the Belgian Hematological Society is pending.

New website!

Please check the brand new website of the Belgian Hematological Society: www.bhs.be



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For complete product information please visit our booth at the exhibition.

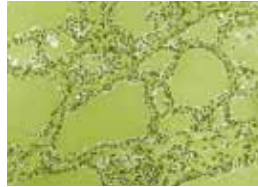
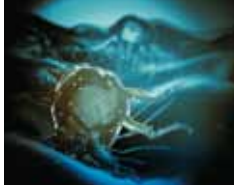


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