

English

Indications for use

This product is indicated for the subcutaneous infusion of insulin from an infusion pump.

Contraindications

Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion of the infusion of blood or blood products.

Warnings

Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site. Before insertion, clean the insertion site with isopropyl alcohol.

Carefully remove the needle guard before inserting the infusion set. Do not bend the needle prior to insertion, and do not use the infusion set if the needle is bent or has been damaged.

If using this infusion set for the first time, do the first setup in the presence of your healthcare professional.

Do not leave air in the infusion set. Prime completely.

Check frequently to make sure the needle remains firmly in place as you may not feel pain if it puts out. The needle must always be completely inserted to receive the full amount of medication.

If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the needle becomes fully or partially dislodged from the skin.

Replace the infusion set every 48 hours, or per your healthcare professional's instructions.

Never prime the set or attempt to free a clogged line while the set is inserted. You may accidentally injure too much medication.

Do not put disinfectants, perfumes, or deodorants on the infusion set and these may affect the integrity of the set.

Dispose of the infusion set as needed safely, in a sharps container, after a single use. Do not clean or re-sterilize.

This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the package has been opened or damaged. (For Paradigm users, do not use the infusion set if the tubing connector needs has

been damaged.) Store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or inside a vehicle.

Use aseptic techniques when temporarily disconnecting the set and consult your healthcare provider on how to compensate for missed medication when disconnected.

If using insulin, carefully monitor your blood glucose levels when disconnected and/or reconnecting.

If using insulin, and your blood glucose level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and/or leaks. If in doubt, change the infusion set because the needle may be dislodged, and/or partially clogged. Should any of these problems arise, make a plan with your healthcare professional for rapidly replacing insulin. Test your blood glucose level to make sure the problem is corrected.

If using insulin, do not change the infusion set just before bedtime unless you can check your blood glucose 1-3 hours after insertion. Reuse of the infusion set may cause damage to the cannula/needle and lead to infection, site irritation, and/or inaccurate medication delivery.

If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly prime the infusion set. **This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.** If this occurs, start over with a new reservoir and infusion set.

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Français

Indications

Ce produit est destiné à la perfusion en sous-cutané de l'insuline avec une pompe à perfusion.

Contre-indications

Les cathéters sont conçus uniquement pour une utilisation en sous-cutané et non pour une utilisation en intraveineuse (IV) ni pour la perfusion de sang ou autre produit sanguin.

Avertissements

Une perfusion médicamenteuse inappropriée, une infection et/ou une irritation locale au niveau du site d'insertion, peuvent être provoquées par une insertion inadéquate et un mauvais entretien du site d'insertion.

Avant l'insertion, nettoyez le site d'insertion avec de l'alcool isopropyle.

Retirez délicatement la protection de l'aiguille avant d'insérer le cathéter. Ne pas plier l'aiguille avant de l'insérer et ne pas utiliser le cathéter si l'aiguille a été pliée ou endommagée.

Si ce cathéter est utilisé pour la première fois, nous recommandons de l'insérer en présence du professionnel de santé.

Assurez-vous qu'il n'y a pas d'air dans le cathéter. Purgez le cathéter complètement.

Vérifiez régulièrement que l'aiguille reste parfaitement en place. Il est possible que celle-ci se déconnecte sans aucune douleur. L'aiguille doit toujours être entièrement insérée pour permettre la diffusion de la totalité du médicament.

En cas d'inflammation du site d'insertion, remplacez le cathéter et utilisez un nouveau site jusqu'à ce que le site précédent soit guéri. Remplacez le cathéter si le pansement se relâche ou si l'aiguille sort entièrement ou partiellement de la peau.

Remplacez le cathéter toutes les 48 heures ou suivant les instructions du professionnel de santé.

N'effectuez jamais de purge du cathéter et n'essayez pas de libérer une tubulure obstruée tant que le cathéter est inséré. Ceci peut provoquer une injection accidentelle et excessive du médicament.

Ne mettez pas de désinfectant, parfum ou déodorant sur le cathéter, ceux-ci pouvant endommager l'intégrité du cathéter.

Après chaque utilisation, jetez le cathéter et l'aiguille dans un conteneur à aiguilles. Ne les nettoyez pas et ne les restérilisez pas.

Ce produit est stérile et apyrogène, sauf si son emballage a été ouvert ou endommagé.

Ne pas l'utiliser si l'emballage a été ouvert ou endommagé. (Pour les utilisateurs d'une pompe Paradigm, n'utilisez pas le cathéter si l'aiguille de la connexion de la tubulure a été endommagée.)

Conservez les cathéters dans un endroit frais et sec. Ne laissez pas les cathéters exposés en plein soleil ou à l'intérieur d'un véhicule.

Utiliser des techniques aseptiques pour déconnecter le cathéter temporairement et consulter le médecin traitant pour savoir comment compenser le volume de médicament manquant pendant cette interruption.

En cas d'injection d'insuline, contrôler attentivement la glycémie lors de la déconnexion et après avoir reconnecté le cathéter.

En cas d'injection d'insuline, et si la glycémie est soudainement élevée ou si une alarme d'occlusion se déclenche, vérifiez l'absence d'obstructions et/ou de fuites.

En cas de doute, remplacez le cathéter car l'aiguille peut être désinsérée ou partiellement obstruée.

Si l'un de ces problèmes survient, prévoyez avec votre professionnel de santé le remplacement rapide de l'insuline. Contrôlez le niveau de glycémie pour vérifier que le problème est résolu.

En cas d'injection d'insuline, ne changez pas de cathéter juste avant de vous coucher, sauf si la glycémie peut être contrôlée 1 à 3 heures après l'insertion du cathéter.

La réutilisation du cathéter peut endommager la canule/l'aiguille et peut provoquer une infection, une irritation au niveau du site d'insertion et/ou une perfusion médicamenteuse inappropriée. Évitez que de l'insuline ou tout autre liquide rentre dans la connexion de la tubulure ; ceci peut bloquer temporairement les orifices qui permettent à la pompe de purger le cathéter correctement. **Il peut en résulter une administration insuffisante ou excessive d'insuline, ce qui peut entraîner une hyperglycémie ou une hypoglycémie.** La cas échéant, recommencez avec un nouveau réservoir et un cathéter.

Remplacez le cathéter toutes les 48 heures ou suivant les instructions du professionnel de santé.

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Deutsch

Einsatzbereich

Dieses Produkt ist für subkutanen Infusion von Insulin mithilfe einer Insulinpumpe indiziert.

Kontraindikationen

Infusionssets sind ausschließlich für subkutanen Infusion, nicht jedoch zur intravenösen (IV) Infusion oder zur Infusion von Blut oder Blutprodukten indiziert.

Warnhinweise

Bei unsachgemäßer Einführung des Infusionssets oder unzureichender Pflege der Einführstelle kann es zu falsch dosierter Arzneimittelabgabe, zu Infektionen und zu Irritationen an der Einführstelle kommen.

Reinigen Sie vor dem Einführen die Einführstelle mit Isopropylalkohol.

Entfernen Sie vor dem Einführen des Infusionssets vorsichtig den Nadelschutz.

Biegen Sie die Nadel nicht vor dem Einführen und verwenden Sie das Infusionsset nicht, wenn die Nadel gebogen oder beschädigt ist.

Führen Sie bei erstmaliger Verwendung dieses Infusionssets die Einrichtung unter Aufsicht Ihres Arztes durch.

Stellen Sie sicher, dass das Infusionsset keine Luft mehr enthält. Vollständig füllen.

Prüfen Sie das installierte Infusionsset gemäß den Anweisungen Ihres Arztes aus, um sicherzustellen, dass die Nadel richtig in der vorgeesehenen Stelle bleibt. Es könnte sein, dass Sie ein Herausströmen der Nadel nicht bemerken, da dies nicht unbedingt sehr schmerzhaft ist. Die Nadel muss immer ganz in die Haut eingeführt sein, damit die vollständige Arzneimittelmenge abgegeben wird.

Wenn die Infusionsstelle entzündet, wenn sich wechsen Sie das Infusionsset unverzüglich aus und verwenden Sie eine andere Einführstelle, bis die Entzündung vollständig verschwunden ist. Wechseln Sie das Infusionsset aus, falls das Band locker wird oder die Nadel teilweise oder ganz aus der Haut herausströmt.

Wechseln Sie das Infusionsset alle 48 Stunden gemäß den Anweisungen Ihres Arztes aus.

Führen Sie niemals einen Füllvorgang durch und versuchen Sie nie, eine verstopfte Leitung wieder durchlässig zu machen, so lange das Infusionsset eingeführt ist. Es könnte dabei eine Überdosierung des Arzneimittels kommen.

Das Infusionsset darf nicht mit Desinfektionsmitteln, Parfums oder Deodorants

in Berührung kommen, da diese Substanzen das Set beeinträchtigen könnten.

Entsorgen Sie das Infusionsset und die Nadel nach einmaliger Verwendung im Abfallbehälter für spitze und scharfe Abfälle. Nicht reinigen oder resterilisieren.

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Bei geschlossener und unbeschädigter Verpackung ist das Instrument steril und nichtpyrogen. Das Infusionsset darf nicht verwendet werden, wenn die Verpackung bereits geöffnet wurde oder Anzeichen für Beschädigungen aufweist. (Für Paradigm-Anwender: Verwenden Sie das Infusionsset nicht, wenn die Katheterschlussnadel beschädigt ist.)

Das Infusionsset an einem kühlen und trockenen Ort aufbewahren. Infusionssets nicht direktem Sonnenlicht aussetzen und nicht im geparkten Fahrzeug lassen.

Behandeln Sie die Haut aseptisch, wenn Sie das Set vorübergehend vom Körper trennen und fragen Sie Ihren Arzt, inwiefern Sie die durch das Trennen nicht zugeführte Arzneimittelmenge kompensieren können/sollten.

Falls Sie Insulin infundieren, müssen Sie Ihren Blutzuckerspiegel sowohl nach dem Trennen als auch nach dem Wiederanschließen des Infusionssets sorgfältig kontrollieren.

Falls Sie Insulin infundieren, und Ihr Blutzuckerspiegel unerklärlich ansteigt oder ein Okklusionsalarm auftritt, kontrollieren Sie das Set auf Verstopfungen oder auf Leckage.

Wechseln Sie im Zweifelsfall das Infusionsset aus, denn die Nadel könnte verformt oder teilweise stopft sein. Sprechen Sie im Falle solcher Probleme mit Ihrem Arzt darüber, wie Sie das entgangene Insulin schnellstmöglich zuführen können. Prüfen Sie Ihren Blutzucker, um sicherzugehen, dass das Problem behoben ist.

Falls Sie Insulin infundieren, wechseln Sie das Infusionsset nicht kurz vor dem Schlafengehen aus, wenn Sie nicht bereit sind in der Lage sind Ihren Blutzuckerspiegel 1–3 Stunden nach dem Einführen des Sets zu kontrollieren.

Das Wiederverwenden des Infusionssets kann die Kanüle und/oder die Einführstelle zu Irritationen und/oder Infektionen an der Einführstelle und/oder zu einer falsch dosierten Arzneimittelabgabe führen.

Wenn die Einführstelle entzündet, wenn sich wechsen Sie das Infusionsset unverzüglich aus und verwenden Sie eine andere Einführstelle, bis die Entzündung vollständig verschwunden ist. Wechseln Sie das Infusionsset aus, falls das Band locker wird oder die Nadel teilweise oder ganz aus der Haut herausströmt.

Wechseln Sie das Infusionsset alle 48 Stunden gemäß den Anweisungen Ihres Arztes aus.

Führen Sie niemals einen Füllvorgang durch und versuchen Sie nie, eine verstopfte Leitung wieder durchlässig zu machen, so lange das Infusionsset eingeführt ist. Es könnte dabei eine Überdosierung des Arzneimittels kommen.

Das Infusionsset darf nicht mit Desinfektionsmitteln, Parfums oder Deodorants

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Español

Indicaciones de uso

Este producto está indicado para la infusión subcutánea de insulina mediante una bomba de infusión.

Contraindicaciones

Los equipos de infusión están indicados sólo para el uso por vía subcutánea y no para infusión intravenosa (i.v.) ni para la infusión de sangre o hemoderivados.

Advertencias

La inserción incorrecta y el mantenimiento inadecuado de la zona de infusión pueden hacer que la administración de la medicación no sea exacta o pueden causar infección o irritación en dicha zona.

Antes de lavar e cabo la inserción, limpie la zona de inserción con alcohol isopropílico.

Retire con cuidado el protector de la aguja antes de insertar el equipo de infusión. No doble la aguja antes de insertarla, y no utilice el equipo de infusión si la aguja está doblada o se ha dañado.

En el caso de que esté utilizando este equipo de infusión por primera vez, haga el primer montaje en presencia de su equipo médico.

No deje aire en el equipo de infusión. Cebelo por completo.

Compruebe con frecuencia que la aguja permanece insertada firmemente, ya que es posible que no sienta dolor si la aguja se sale. La aguja debe estar siempre insertada por completo para que usted pueda recibir la cantidad completa de medicación.

Si el área de infusión se inflama, sustituya el equipo y use una nueva zona de inserción hasta que la primera se haya curado. Sustituya el equipo si la cinta se afloja o si la aguja se saliera total o parcialmente de la piel.

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